جمهوری اسلامی ایران
وزارت بهداشت درمان و آموزش پزشکی

فرم درخواست راه‌اندازي نظام ثبت بيماري‌ها

مركز توسعه و هماهنگي تحقيقات

معاونت تحقيقات و فناوري

Title of Registry:
Parkinson's Disease Registry in Patients Referred to Neurology Clinics of Shahid Beheshti University of Medical Sciences in Tehran (SBMU-PDR)

Proposer (s):
Mehri Salari

Research center/Hospital/Organization:
Functional Neurosurgery Research Center,
Shohada-e-Tajrish Neurosurgical Center of Excellence,
Shohada-e-Tjrish hospital

University/Department:
Department of Neurology, Shahid Beheshti University of Medical Sciences

Part I: Registry Certificate

Title of Registry:

Parkinson's Disease Registry in Patients Referred to Neurology Clinics of Shahid Beheshti University of Medical Sciences in Tehran (SBMU-PDR)

Main director of registry (Principal Supervisor): Mehri Salari
Organisation/Hospital/Research center:
Shohada-e-Tjrish hospital
Loghman Hospital
Imam-hosein Hospital
Department/University:
Department of Neurology,Shahid Beheshti University of Medical Sciences
Where the project is done:

Duration of project: 5 years

Strategic (scientific) Committee (Board) :
Alireza Zali, MD
Mehri Salari, MD
Farzad Ashrafi, MD

Abstract: Back ground, Statement of Problem & Significance

Among degenerative neurological disease, Parkinson Disease (PD) is the second most common disorder. Although a wide range of incidence and prevalence rate exist in reviewed literatures due to a consequence of variation in study methodologies, the crude prevalence rate above 60-year-old is 1%. Increase in aging population will lead to an increase in PD patients. The PD registry will be used to facilitate the understanding of basic epidemiological features of the disease, genetic and non-genetic risk factors, co-morbidity, the up-to-date treatment strategies and the related economic burden from medical and surgical treatment (deep brain stimulation), to develop new therapeutic protocols as well as healthcare policies, and ultimately, to improve the quality of life of PD patients. PD registry will also be served as data bank for investigators in the field of PD to quickly identify and notify research subjects about other research studies for which they are eligible.

Abstract: Methodology:

The 3 main university hospitals including: Shohada-e-Tajrish, Loghman, and Imam Hossein will serve as representative of pilot study for PD registry. This will be a record-based, multi-center, nation-wide, cohort study. A user-friendly, yet, encrypted registration platform will be provided through internet for authorized personnel. The contents of PD registry will be as follow: demographic features, risk factors, clinical profiles of diagnostic criteria, co-morbidity, images profiles, and treatment regimens in details.

Part II: Profile of Project Partners

1- **Name of the Principal Supervisor**: Mehri Salari
2- **The name of degree sought:** Associate professor
3- **Workplace:** Shohade-e-Tajrish Hospital
4- **Workplace address:** Tajrish SQ, Shohada-e-Tajrish Hospital
5- **E-mail:** mehri.salari@gmail.com
6- **Mobile phone number:** 09124972186
7- **Workplace phone number:**

8- **Profile of Project Partners:**

Workplace phone number & address	University/Department	Degree	Name	N.
Neurology department, Loghman Hakim Hospital Makhsoos St, South Karegar Ave, Tehran, Iran Tel: (+98) - 21 - 5541 - 9005(-11)	Shahid Beheshti University of Medical Science	Professor of Neurology	Hosein Pakdaman	**1**

2	Kurosh Gharagozli	Professor of Neurology	Shahid Beheshti University of Medical Science	Neurology department, Loghman Hakim Hospital Makhsoos St, South Karegar Ave, Tehran, Iran Tel: (+98) - 21 - 5541 - 9005(-11)
3	Mahtab Ramezani	Assistant Professor of Neurology	Shahid Beheshti University of Medical Science	Neurology department, Loghman Hakim Hospital Makhsoos St, South Karegar Ave, Tehran, Iran Tel: (+98) - 21 - 5541 - 9005(-11)
4	Omid Hesami	Assistant Professor of Neurology	Shahid Beheshti University of Medical Science	Neurology department, Imam Hossein Hospital, Madani Ave, Tehran, Iran Tel: (+98)-21- 7755- 8081
5	Pegah Soltani	Medical Student	Shahid Beheshti University of Medical Science	School of Medicine, Koodakyar St. Danshjoo Blv, Velenjak, Shahid Chamran Highway, Tehran, Iran Tel: (+98)- 9136530805

Part III: Details of Registry Project

1- **Project Title in Persian:**

ثبت بیماری پارکینسون در بیماران مراجعه کننده به درمانگاه های نورولوژی وابسته به دانشگاه علوم پزشکی شهید بهشتی در شهر تهران

2- **Project Title in English:**

3- Parkinson's Disease Registry in Patients Referred to Neurology Clinics of Shahid Beheshti University of Medical Sciences in Tehran (SBMU-PDR)

4- **Registry Type:**

Disease/complication

5- **Geographic Range of Registry:**

Hospital

Hospital name:

Shohada-e-Tjrish hospital
Loghman Hospital
Imam-hosein Hospital

6- **Main Objectives:**

To register cases of Parkinson disease and understand associated causes and risk factors for Parkinson Disease

-To establish a referral center for accurate and definitive diagnosis of Parkinson disease

-To establish a referral center for Parkinson disease patients follow up in specific time intervals

-To establish a referral center for diagnosing cases which require treatment

-To establish a referral center for providing health care for Parkinson disease patients

-To establish a referral center for providing rehabilitation care for Parkinson disease patients

-To follow up Parkinson disease patients on regular intervals and determining disease outcomes, mortality rate and causes of death

-To attempt to attract specialist and specialist physicians from around the country to refer Parkinson's patients to the center and help with disease registration

-To establish a referral center for enrolling people with Parkinson disease into new research studies

7- **Research Objectives:**

-To evaluate treatment efficacy, resulting quality of life of an applied therapy (or treatment) and ensure compliance with treatment indicators and criteria in Parkinson disease patients

-To develop new therapeutic protocols for Parkinson disease patents

-To increase knowledge about the prevention strategies of Parkinson’s disease

-To analyze gathered data for quality control and clinical improvement as part of an overall quality improvement strategy To contribute to equitable and high quality care for people with Parkinson Disease

-To develop new healthcare policies for Parkinson disease patients

8- **Definition of the Disease/Complication (Inclusion & Exclusion criteria):**

Parkinson's disease (2019 ICD-10-CM Diagnosis Code G20) is a progressive nervous system disorder that affects movement. Symptoms start gradually, sometimes starting with a barely noticeable tremor in just one hand. Tremors are common, but the disorder also commonly causes stiffness or slowing of movement. In the early stages of Parkinson's disease, your face may show little or no expression. Your arms may not swing when you walk. Your speech may become soft or slurred. Parkinson's disease symptoms worsen as your condition progresses over time. Although Parkinson's disease can't be cured, medications might significantly improve your symptoms. Occasionally, your doctor may suggest surgery to regulate certain regions of your brain and improve your symptoms.

Parkinson's disease signs and symptoms can be different for everyone. Early signs may be mild and go unnoticed. Symptoms often begin on one side of your body and usually remain worse on that side, even after symptoms begin to affect both sides.

Parkinson's signs and symptoms may include:

Tremor. A tremor, or shaking, usually begins in a limb, often your hand or fingers. You may a rub your thumb and forefinger back-and-forth, known as a pill-rolling tremor. Your hand may tremor when it's at rest.

Slowed movement (bradykinesia). Over time, Parkinson's disease may slow your movement, making simple tasks difficult and time-consuming. Your steps may become shorter when you walk. It may be difficult to get out of a chair. You may drag your feet as you try to walk.

Rigid muscles. Muscle stiffness may occur in any part of your body. The stiff muscles can be painful and limit your range of motion.

Impaired posture and balance. Your posture may become stooped, or you may have balance problems as a result of Parkinson's disease.

Loss of automatic movements. You may have a decreased ability to perform unconscious movements, including blinking, smiling or swinging your arms when you walk.

Speech changes. You may speak softly, quickly, slur or hesitate before talking. Your speech may be more of a monotone rather than with the usual inflections.

Writing changes. It may become hard to write, and your writing may appear small.

The diagnosis of Parkinson’s disease (PD) is based on clinical features and differently to the common opinion that detecting this condition is easy, seminal clinicopathological studies have shown that up one-fourth of patients diagnosed as PD during life has an alternative diagnosis at postmortem. The misdiagnosis is even higher when only the initial diagnosis is considered, since the diagnostic accuracy improves by time, during follow-up visits. Given that the confirmation of the diagnosis of PD can be only obtained through neuropathology, to improve and facilitate the diagnostic–therapeutic workup in PD, a number of criteria and guidelines have been introduced in the last three decades. In the present paper, we will critically re-appraise the main diagnostic criteria proposed for PD, with particular attention to the recently published criteria by the International Parkinson and Movement Disorder Society (MDS) task force, underlying their novelty and focusing on the diagnostic issues still open. We also emphasize that the MDS-PD criteria encompass the two main previous sets of diagnostic criteria (United Kingdom PD Society Brain Bank and Gelb’s criteria), introducing at the same time new aspects as the use of non-motor symptoms as additional diagnostic features, and the adoption of the concept of prodromal PD, crucial to enroll in clinical trials PD patients in the very early phase of the disease. To better understand the real diffusion of the new MDS-PD diagnostic criteria among neurologists, we have also collected selective opinions of sixteen movement disorder experts from various world regions on their practical approach for the clinical diagnosis of PD. Results from this brief survey showed that, although innovative and complete, the revised diagnostic criteria produced by MDS task force are still scarcely employed among clinicians. We believe that both national and international scientific societies should operate in the future for a broader diffusion of these criteria with specific initiatives, including dedicated events and teaching courses.

9- Study Population:

Patients with Parkinson diagnosis based on clinical features which were referred to the 3 Shahid Beheshti university hospitals (Shohada-e-tajrish, Imam Hossein, Loghman), and all patients who received Levodopa tablet according to the national Pharmaceutical data.

10- Sample size:

Given the lack of accurate statistics on the incidence and annual prevalence of Parkinson disease in the country, it is difficult to estimate the expected average annual number of patients in a given period (5 years). According to statistics from the number of referrals to the 3 Shahid Beheshti university hospitals so far, the number of cases for the first year is estimated to be 1000, with an average of 300 each year.**Data sources:**

11- Data sources:

Primary data sources:

-Questionnaire forms filled out by the plan partners for patients with definite diagnosis of Parkinson's referred to the 3 Shahid Beheshti University Hospitals neurology clinics.

-Pharmaceutical data bank of Ministry of Health and Medical Education of Iran

Secondary data source:

Information on disease progression, response to treatment, morbidity or mortality during follow-up of patients will be recorded in the patient's file by the plan partners in neurology clinics of the 3 Shahid Beheshti University Hospitals.

12- Case Finding:

Patient-tracking is done by informing and co-operating physicians across the country with the aim of introducing and referring patients to the 3 Shahid beheshti University Hospitals to record the characteristics of disease, regular follow-up of patient , complications of the disease and mortality rate by relevant staff and physicians.

The 3 main university hospitals including: Shohada-e-Tajrish, Loghman, and Imam Hossein will serve as representative of pilot study for PD registry. A user-friendly, yet, encrypted registration platform will be provided through internet for authorized personnel. Informing is done through the mass media and the Functional Neurosurgery Research Center's website for patients and physicians to gain collaboration and increase patient referrals.

13- Patient follow up:

Patients will be asked for updates to both biographical and medical information every year. This will ensure that we have the most up-to-date information on the patient file. These one-year updates can be done by in person interview, mail-in questionnaires or over the phone.

14- Back ground, Statement of Problem & Significance

Parkinson’s disease (PD) is a long-term degenerative disorder of the central nervous system and affects 1–2 per 1000 of the population at any time. PD is characterized by its main motor symptoms bradykinesia, rigidity and tremor, but also have additional motor and non-motor characteristics. The onset of the disease is usually at an age of 65 to 70 years. PD was originally considered a pure movement disorder with three cardinal signs: tremor, rigidity and bradykinesia. Over the years postural changes in general and postural instability in particular was used as a fourth cardinal sign. During the 1990s it became apparent that a considerable proportion of cases with a clinical diagnosis of PD did not fulfill histopathological PD criteria at autopsy, even at the most experienced hands. Several studies report data on the epidemiology of PD. However, methodological differences between studies make direct comparison of prevalence estimates difficult. It is generally accepted that the disease affects 1% of the population above 60 years. PD is rare before age of 50 years and reaches a prevalence of 4% in the highest age groups. There is no cure for Parkinson's disease, but medications, surgery, and physical treatment can provide relief. There is little prospect of significant new PD treatments in the near future. Currently active research directions include the search for new animal models of the disease and studies of the potential usefulness of gene therapy, stem cell transplants and neuroprotective agents.

Registration systems for diseases and other health outcomes provide important resource for biomedical research, as well as tools for public health surveillance and improvement of quality of care. According to the World Health Organization (WHO), patient registry is a file of documents containing uniform information about individual persons, collected in a systematic and comprehensive way, in order to serve a pre-determined scientific, clinical or policy purpose. The Ministry of Health and Medical Education (MOHME) of Iran launched a national program to establish registration systems for different diseases and health outcomes. The advantages of registry-based include addressing a large study size and diverse group of patients in several treatment centers. In addition, they have no restrictions for evaluation of concurrent treatments and co-morbidities, and consider an extended time-frame in their evaluation and provide evidence for effectiveness of treatments in the real world. Data from registries may generate several hypotheses that can be tested by clinical trials and other analytical methods. Policy makers apply the data from patient registries to understand the etiology of diseases in the target population, evaluate treatments pattern, conduct safety surveillance and study different outcomes to demonstrate the value of the interventions.

There are no reports on the incidence of PD in Iran Much work remains to bring patients new and improved treatments for Parkinson's.in PD registry system, we are aiming to identify the disparities in Parkinson’s disease risk, demographic features and clinical characteristics of a huge number of patients with PD in Tehran, Iran. Data about age of onset, family history, past medical history, and Parkinsonism symptoms will be collected and reported in this project.

15- Review of literature:

There are no Parkinson Disease databases reported from Iran and only a few studies have reported clinical characteristics and demography of the disease in the region/country.

Roohani et al. reported the demographic characteristics of 1656 Iranian patients with PD who were referred to the movement disorder clinic in a large cross-sectional study. Based on the current study, male to female ratio among Iranian PD patients is 2.1:1, which is much higher than reports from other countries. Investigation about the cause of this observation warrant further study. Although this study had a large number of participants, it had some limitations such as retrospective design, short number of variables and lack of patient's follow up which should be considered and corrected in futures studies.[1]

Salari et al. described the clinical profile of 987 patients with PD in Isfahan Province. However, the data were only collected from neurology clinics. Determining the diagnosis of PD by neurologists specialized in movement disorders validates this study. The researchers tend to conduct a comprehensive door-to-door country based study in order to determine the exact incidence of PD in Iran. As the Iranian population becomes older, the incidence rate of PD is expected to increase in the future, requiring optimal planning for healthcare and facilities for these patients. In this study, all patients referred to the neurologists were examined by a movement disorder specialist, which was one of the advantages of the study. Therefore, patients with atypical Parkinsonism were excluded. [2]
There are similar reports for PD registry from other countries around the world.
The American Parkinson Disease Association (APDA) and The Michael J. Fox Foundation for Parkinson's Research (MJFF) are co-funding the Nebraska Parkinson's Disease Registry with a three-year commitment. The funding reinstates the Nebraska Registry (suspended in October 2004 for budgetary reasons), allowing researchers to collect data with accurate, historical and current information on Parkinson's patients. The Nebraska Parkinson's Disease Registry was the first operational registry for the disease in the United States, offering researchers a valuable tool in amassing epidemiological data. The Registry has already allowed researchers to measure prevalence in the urban Omaha area versus the less populated agricultural central and western regions. The Nebraska Registry develops a resource for recruiting a valid sample for assessing exposure to a wide range of risk factors.[3]
The California Parkinson’s Disease Registry Act (CPDRA) was enacted in late 2004. This legislation mandates the State Department of Health Services (CDHS) Director to conduct a program of epidemiological assessments of the incidence of PD (including monitoring associated with suspected chemical agents encountered by the public in general and occupational environments) and create a database of persons with this disease for research purposes.[3]
In 2015 the State of Utah designated Parkinson’s disease (PD) as a reportable disease. The University of Utah, Department of Neurology, worked with the Utah Department of Health to launch the Utah Parkinson’s Disease Registry (UPDR). The purpose of the UPDR is to develop a database of accurate historical and current information for research and public health purposes. The collection of patient data is important for detecting disease incidence, and possible risk factors of PD and other related movement disorders. The UPDR is committed to collecting high quality data for population research only. Data security measures are in place to assure privacy and confidentiality of the information.[4]
The Washington State Parkinson Disease Registry represents a collaboration between Washington physicians and researchers and Parkinson advocacy groups. It was created in May 2007 , directed by Dr. Cyrus Zabetian and based at the University of Washington and the VA Puget Sound Health Care System in Seattle. The Registry is currently funded by the American Parkinson Disease Association (APDA) - Northwest Chapter. The purpose of the Washington State Parkinson Disease Registry is to make Parkinson disease (PD) research happen faster by connecting people with Parkinson disease to the research community.[5]
The Australian Parkinson’s Disease Registry (APDR) is a collaborative endeavour set up by researchers across Victoria, Western Australia and New South Wales, and is managed by the Cooperative Research Centre (CRC) for Mental Health. The registry consists of two distinct cohorts: a cohort of volunteers with Parkinson’s disease (N = 314) and a cohort of volunteers with no signs of Parkinson’s disease (N = 103), both of whom have provided blood and biological samples for use as a research platform for Australian and international researchers. Additionally, the participants with Parkinson’s disease have been phenotyped using the Unified Parkinson’s Disease Rating Scale (UPDRS) and other clinical scales, while a brief family history of Parkinson’s disease is available for healthy controls. This data is currently within the Mediaflux Digital Asset Management System operated by Research Platform Services, University of Melbourne. The Australian Parkinson's Disease Registry data and samples will be used in future investigations to discover and validate biomarkers for diagnosis and for monitoring the effects of therapies for Parkinson’s disease and other forms of neurodegenerative disease, including in particular, those associated with movement disorders. More broadly, the data will also be useful in large scale investigations of genetic factors

and other biological mechanisms that may be involved in the etiology of Parkinson’s disease and/or in determining the trajectory of disease in individuals.[6]

Swedish Neuro Registries is a quality register with the aim of ensuring that neurological care is equitable and of high quality and to ensure treatment guidelines are being followed. Swedish Neuro Registries are represented in all counties and all hospitals where neurological care is provided. It will be the base for national neurological research. The registry started as an MS registry in 1996. In 2012, it became Swedish Neuro Registries with 8 diagnosis: Multiple Sclerosis, Parkinson’s disease, Myasthenia Gravis, Narcolepsy, Epilepsy, Motor Neuron Disease, Inflammatory Polyneuropathy and Severe Neurovascular Headache. The registry for Parkinson’s disease is a national quality registry that aims to contribute to Swedish Parkinson’s care by spreading new knowledge through research and education.[7]

The Thailand Parkinson's Disease Registry is a new resource, and data collection began in March 2008. Data is collected by the Registry from physicians, and a mechanism is also provided for patients to self-report. There is underreporting because of poor record keeping and administrative procedures in some facilities, and there is an unknown number of persons with PD who are not properly diagnosed because of inadequate facilities and staffing in some areas. As of March 2011, the Thailand PD Registry had identified 40,049 PD patients. The combination of a passive registry and the CRM technique allowed us to derive population prevalence estimates for PD in Thailand. Thai PD prevalence estimates were similar to previous ones published for Asian countries; in addition, they suggested that urbanization and exposure to pesticides may both be risk factors for PD in the Thai population.[11]

In addition to mentioned large scale registries, also there are several reports from different countries which have under estimated prevalence, clinical demography and treatments for Parkinson disease in specific regions/countries.

Parkinson's Disease Registry （PDR) is an Observational [Patient Registry]. The purpose of the Parkinson's disease Registry (PDR) is to develop a nation-wide database of persons with Parkinson's disease (PD) in Taiwan. The PDR will be used to facilitate the understanding of basic epidemiological features of the disease, genetic and non-genetic risk factors, co-morbidity, the up-to-date treatment strategies and the related economic burden from medical and surgical treatment (deep brain stimulation), to develop new therapeutic protocols as well as healthcare policies, and ultimately, to improve the quality of life of PD patients. PDR will also be served as data bank for investigators in the field of PD to quickly identify and notify research subjects about other research studies for which they are eligible. Patient who registered can also sign their consent for a future brain donation after they passed away.[12]

Other small scale PD registry examples are: Mexican Registry of PD (ReMePARK), Framingham study, the East Boston study, and EURODEM, Parkinson's New Zealand, Parkinson disease in Navarre, Parkinson Nigeria.

There is also an ever increasing attention to Parkinson disease and more registries have been started in recent years all over the world. Last fall, the NeuroPoint Alliance (NPA) joined together with the Parkinson’s Study Group (PSG), Neurotargeting and the Michael J. Fox Foundation (MJFF) to launch the Registry for the Advancement of Deep Brain Stimulation in Parkinson’s disease (RAD-PD). This is the latest registry project of the NPA, which currently maintains other registry projects, including the QOD-Spine and the Stereotactic Radiosurgery registries. The launch of RAD-PD represents a unique partnership between neurologists and neurosurgeons with support from MJFF. The registry enrolled its first patients in March, just prior to Parkinson’s disease Awareness month in April. The goal of RAD-PD is to create the largest cohort of comprehensively characterized patients with Parkinson’s disease (PD) who have contemplated or undergone deep brain stimulation (DBS) surgery, and longitudinally follow them for five years or more.[8]

Calgary Parkinson Research Initiative (CaPRI) is a major research initiative that will allow the University of Calgary to become a major hub for clinical research in the field of Parkinson’s disease (PD) and related disorders.

CaPRI has been made possible by a generous contribution from a member of the community.

Initially, one of the main components of CaPRI will be a registry that will allow any patient in southern Alberta with PD or a related disorder to become a research participant. This registry wil be linked to an anonimised database and biobank containing detailed clinical information, blood anaylsis and imaging data amongst others. The goal of CaPRI is to create a registry and database that will allow researchers to conduct better quality studies in the

understanding and development of tests to diagnose and improve treatments for people with Parkinson's disease (PD).[9]
Parkinson Québec is Quebec Parkinson Network (QPN) partner, an organization whose main mission is to promote multidisciplinary research on Parkinson's disease. QPN has established the participant registry, a database of participants that centralizes people with Parkinson's disease who wish to participate in research projects. Thanks to QNP, Quebec's researchers and clinicians are in touch with these participants interested and available to participate in research studies.[10]

It was recently announced that The San Diego State legislature is debating including $10 million into the state budget to fund a Parkinson's disease registry that was created by law in 2017 that will help scientists discover a cure.[13]

16- Methodology, Validity & Reliability of Issues:

The Neuroscience Research Centers at Shohada-e-Tjrish, Loghman, Imam Hossein hospitals, led by Dr Mehri Salari and with the help of a team of trained staff, specialists, strive to provide research and medical care to patients. Biographical information of patients and their clinical information will be registered by the patient and his/her physician respectively. All the patients will be re-evaluated in definite intervals and their information will be updated. A user-friendly, yet, encrypted registration platform will also be provided through internet for authorized personnel. All questionnaires are reviewed weekly by the questioner's supervisor. Monthly written reports of demographical and clinical data registered is given to the main director of the registry and reviewed by scientific committee every six months. After data collection by the registrar, analysis is performed by epidemiology and statistics specialists in collaboration with neurology specialists. Data quality assurance, quality adjustment of registration processes, and quality adjustment of software systems are regularly reviewed by the Scientific Committee.

17- Data Collection Instrument:

Registry process will occur over the phone or in person interview or a registration platform provided through internet. If a person referred to the neurology clinics of the 3 hospitals has been diagnosed with a Parkinson's disease or a related movement disorder, or if a person has been diagnosed to receive Levodopa treatment, his/her doctor, nurse, physical or speech therapist or a health care facility report his/her Parkinson's diagnosis to the SBMU-PDR. If patient meet the basic criteria for inclusion in the study, we will explain the purpose, procedures, benefits, and risks of participation in this registry plan.Once we verify that patient has provided verbal consent, a registry coordinator will collect the following information:

- Biographical information such as name, address, phone number, date of birth, ethnicity, and email address

- Medical information such as initial and current symptoms related to Parkinson's disease, medications, complications from medications, history of deep brain stimulation (if applicable) and family history of Parkinson's disease

- patient interest in participating in various types of studies such as drug trials, genetics research, studies on environmental exposures, and biomarker research

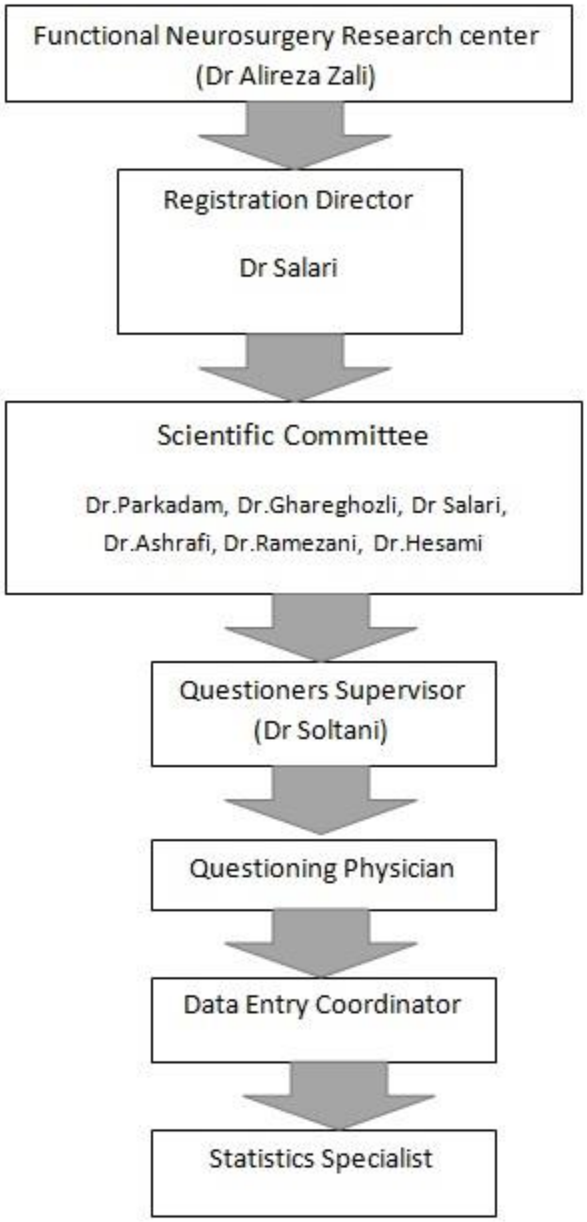
We will also ask for patient legally authorized representative's contact information (phone number, address, email) if different from him/herself. This is necessary since it will facilitate the follow-up / update process.

The interview process will occur over the phone or in person. The interview can be made shorter and easier if patient can prepare a list of medications and doses, physician names, and Parkinson's disease symptoms beforehand.

18- Management Structure:

The Scientific Committee, under the supervision of the Research Assistant of Functional Neurosurgery Research Center, monitors the activity of the questioning physicians. Patient information is provided by the questioning physician in collaboration with the data entry coordinator for the statistics and neurology specialists in order to be analyzed. The Main Registrar will review all requests to use the Registry. The main function of the Main Registrar, is to make sure that only quality studies are allowed to utilize the Registry. Parkinson's disease researchers will go through a rigorous process to access SBMU-PDR data including an approval process by a certified institutional review board. If their application is approved, they will receive only the required information for their approved purpose. SBMU-PDR will only release patient contact information to qualified researchers under tightly controlled circumstances. Policies and procedures for accessing confidential data for SBMU-PDR will be posted on the SBMU-PDR website when available.

19- Management Structure Flowchart:



20- Similar Registry Project(s): -

21- Anonymity and Confidentiality of Subjects

All telephone interviews are conducted in a secure private office and all of the patient’s research records will be kept in locked cabinets and protected computer files. Patient’s information will never be given or sold for advertisement or fund-raising. We will not place patient’s name on any research data or reports of the registry. Instead, we will assign a code number to each patient information and we will keep the master list that links the patient's name to your code number in a locked cabinet. We will not share patient information with anyone unless the patients asks to do, the only exception is if there is a risk of possible harm to others or to the patient himself. Some of the information obtained from patient's participation in other research studies will be given back to us and we will store this information in their Registry records. The Main Registrar will review all requests to use the Registry. The main function of the Main Registrar, is to make sure that only quality studies are allowed to utilize the Registry. Parkinson's disease researchers will go through a rigorous process to access SBMU-PDR data including an approval process by a certified institutional review board. If their application is approved, they will receive only the required information for their approved purpose. SBMU-PDR will only release patient contact information to qualified researchers under tightly controlled circumstances. Ethical principles in patient information registration regarding confidentiality, accessibility and consent for SBMU-PDR according to the Ethics Committee of Shahid Beheshti University of Medical Sciences will be adhered.

22- Ethical Issues;

the registry has a consent form (also sometimes referred to as informed consent or consent to participate) based on the approval of the Ministry of Health and Medical Education, that patients must read and sign before joining the project. The consent form will explain rights and responsibilities of the patient and what to expect during the project. Patients might not be able to provide verbal consent for several reasons, including:

- might have diminished decision-making capacity.

- The disease might have affected their ability to communicate (for example, they may have a soft voice or slurred speech).

Under these circumstances, we will ask their legally authorized representative (guardian, durable power of attorney, spouse, or other next of kin) to provide verbal consent. Volunteers can also request a copy of the consent form to review it in advance of this in-person visit.

23- Design Limitations & solution Methods:

-Careful screening in neurology clinics regardless of patients admitted to the neurology wards of the 3 hospitals of Shahid Beheshti Medical University
-Patients unwillingness to visit their clinician in the clinic frequently
-Patient non-cooperation during interview
-Provide appropriate funding to pay staff salaries
-Provide a user-friendly, yet, encrypted registration platform through internet for authorized personnel
-provide the possibility of patients follow up by telephone or e-mail

24- Bibliography:

1- Roohani M, Ali Shahidi G, Miri S. Demographic study of parkinson's disease in Iran: Data on 1656 cases. Iranian journal of neurology. 2011;10(1-2):19-21.
2- Salari M, Mirmosayyeb O, Etemadifar M, Shaygannejad V, Khorvash F, Najafi MR, et al. Demographic features and clinical characteristics of patients with Parkinson's disease in Isfahan, Iran. Iranian journal of neurology. 2018;17(1):6-10.

3- https://www.michaeljfox.org
4- http://updr.org/

5- https://depts.washington.edu/wpdr/
6- https://melbourne.figshare.com/articles/Australian_Parkinson_s_Disease_Registy
7- https://neuroreg.se/en.html/parkinsons-disease
8- www.rad-pd.org
9- https://brainandmentalhealthclinics.ca/programs/calgary-parkinson-research/
10- http://rpq-qpn.ca/en/research-support/participant-registry/
11- https://www.researchgate.net/publication/51846052_A_National_Registry_to_Determine_the_Distribution_and_Prevalence_of_Parkinson's_Disease_in_Thailand_Implications_of_Urbanization_and_Pesticides_as_Risk_Factors_for_Parkinson's_Disease
12- https://clinicaltrials.gov/ct2/show/study/NCT02051205
13- https://www.kusi.com/parkinsons-resource-organization-registry-funding/

25- Variable Table

Scale	Evaluation(Measurement)	Scientific-Practical Definition of Variable	Qualitative		Quantitative		Variable Type		Variable	N.
			Ordinal	Nominal	Interval	Ratio	Independent	Dependent		
Year	Questionnaire	The length of time that the patient has lived.			*		*		age	1
Male female	Questionnaire	Either of the two sexes (male and female).		*			*		Gender	2
Not educated Diploma associate Bachelor Master doctorate	Questionnaire	To which stage of education has the patient studied based on formal subdivisions of study in Iran.		*			*		education	3
Right handed Left handed	Questionnaire	Patients tendency to use which hand rather than another.		*			*		handedness	4
(Nominal)	Questionnaire	The city where the patient is living now.		*			*		Location city	5
(Nominal)	Questionnaire	The city where patient was born in.		*			*		City of birth (patient)	6
History of Parkinson	Questionnaire	Family history of Parkinson Disease (up to second degree relatives).		*			*		Family history	7

										History of tremor History of rigidity History of bradykinesia
8	City of birth (parents)		*			*		The city which the patients parents were born.	Questionnaire	(Nominal)
9	Neurosurgical history		*			*		Neurosurgical history including type and year.	Questionnaire	(Nominal)
10	Initial symptom		*			*		Initial symptom at onset of disease e.g. bradykinesia, tremor etc.	Questionnaire	Tremor Rigidity bradykinesia
11	Presenting symptom		*			*		Clinical presentations of the patient at the time of registry.	Questionnaire	Tremor Rigidity bradykinesia

26- Activity Plan (Time Table):

N.	Task name	Director	Planned Duration(month				Time plan (months)																	
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15.	16	17	18	19	20	21

Total estimated time(months):

Part IV: Registry Costs

27- Salaries

№	Responsibility	Responsible(s)	degree	Total number of responsibles	Each person salary	total
1						
2						
3						
4						

28- Indirect Costs (laboratory tests/ specialized services) :

Lab test/specialized medical service	Server/center	Total frequency of test	Cost for each time	Total cost(rials)
Total test cost:				

فهرست وسايل و موادي كه بايد از اعتبار اين طرح از داخل يا خارج كشور خريداري شود:

29- Equipment costs:

نام دستگاه	کشورسازنده	شرکت سازنده	شرکت فروشنده ایراني	تعداد لازم	قیمت واحد	**قیمت کل**

موادمصرفي: 30-

نام ماده	کشورسازنده	شرکت سازنده	شرکت فروشنده ایراني	تعداد یا مقدار لازم	قیمت واحد	**قیمت کل**

هزینه هاي دیگر

سایر موارد	ریال

جمع هزينه هاي طرح :

هزينه پرسنلي		هزينه مسافرت	
هزينه آزمايش‌ها و خدمات تخصصي		هزينه هاي ديگر	
هزينه مواد و وسايل مصرفي			
هزينه وسايل غير مصرفي		جمع كل	

منابع تأمین هزینه‌ها: -31

رديف	نام موسسه يا ساير منابع تأمين مالى	ميزان مشاركت	ملاحظات
١			
٢			
٣			
٤			
٥			

.ريال..............0......مبلغي كه از منابع ديگر كمك خواهد شد و نحوه مصرف آن :

.ريال...........باقيمانده هزينه هاي طرح كه تامين آن از معاونت تحقيقات وزارت بهداشت درخواست مي شود :

بخش پنجم: ضمائم

1- نمونه فرم‌ها و دستورالعمل‌های مورد استفاده در ثبت

2- رزومه علمی مسوول اصلی ثبت

3- فرم رضایت آگاهانه در برنامه ثبت

4- فهرست گزارشات و مقالات به چاپ رسیده از منابع داده‌های برنامه ثبت در حال اجرا تا کنون

5- گواهی تأمین اعتبار توسط مرکز، دانشگاه و یا سایر نهادها و سازمان‌ها