



ISLAMIC REPUBLIC OF IRAN



Shahid Beheshti
University of Medical Sciences

Research Affairs
Disease Registry Unit

In the Name of GOD

REGISTRY PROPOSAL:

A. Title of Registry: Data registry of Hematopoietic Stem Cell Transplantation in pediatrics group(0-18 years old) in Shahid Beheshti University of Medical Sciences and Allied centers

B. Brief Intro to Registry –Literature Review (1-2 paragraphs): The outcome registries are organized systems to collect uniform data using an observational study methodology. Patient registries are used to determine specified outcomes for a population for predetermined scientific, clinical, or policy purposes.

Historically, outcome registries established in the development of hematopoietic stem cell transplantation (HSCT) have now evolved into myriads of locoregional and international transplant activity and outcome resources. Over time, these registries have contributed immensely in determining trends, patterns, and treatment outcomes in HSCT. Moving forward, HSCT data collection, and interpretation should be an integral part of the treatment rather than an option. Quality assurance and continuous quality improvement of the data are pivotal for credibility, measurable/quantifiable outcomes, clinically significant impact.

C. Registry Objectives (what is it you are specifically looking at, trying to reach?): HSCT data Registry by following established ethical and quality standards for the design, collection, analysis, reporting, monitoring, and auditing of the registry data and linking with National and International Registry in the world , including Eeuropean HSCT EBMT).

Data registry of Hematopoietic Stem Cell Transplantation in pediatrics group(0-18 years old) in Shahid Beheshti University of Medical Sciences and Allied centers.

Data Registry :

Demographic Data: Age of patient , Sex , Age of Transplantation
Type of disease : Leukemia, Lymphoma , Solid tumor , Metabolic disease,...
Type of HSCT: Allogenic , Autologous
Type of Allo HSCT: MSD, MRD, MUD, Cord blood , Haploidentical
Source of Stem Cell:BM, PB, CB
Conditioning Regimen :Myeloablative(MA) , Reduced Intensity Conditioning(RIC)
Prophylaxis for GVHD :...
GVHD : Acute , Chronic
Short side effects : infections
Late side effects: Second malignancy, Infertility,
Outcome (Remission , Death, Relapse , Rejection)

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D. Registry Design (participants, Data Collection, Statistical Analysis plan, etc.):

Pediatrics group(0-18 years old) in Shahid Beheshti University of Medical Sciences and Allied centers .

- Collection of informations From Charts data record, Interview , by Tel, Email
- Providing Questionnaire & Electronic data Collection
- Analysis of data by statistical Epidemiologist

- Number of patients : 460 during 5 years .

After data collection by educated team in different centers , all data will be evaluated and analysed by statistical Epidemiologist .

E. Timeline for your Registry project (project deadlines set by you and your mentor): 5 years (Jan 2020-jan 2025)

F. Who will provide support and feedback and how often will this occur?

- Support: Pediatric Congenital Hematologic Disorders Research Center .
Research Institute For Children Health, Shahid Beheshti University of Medical Sciences
- Audit:Quality management and performance improvement are pivotal for the outcome registries of any HSCT center. So in this study, Data collection will be evaluated by Auditor annually (1 time / year) during 5 -years of study , for 3–5 days, and database data and patient medical records are compared; consent forms are also checked for patients in the research database sample repository. After the audit, corrections are reflected in the registry database at the data center.

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