

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the clinical and metabolic outcomes of pharmacotherapy based total parental nutrition support in adult patients undergoing bone marrow transplantation

Protocol summary

Summary

The main aim of this study is to evaluate the efficacy of total parental nutrition support in comparison with partial parenteral nutrition in adult patients undergoing bone marrow transplantation that due to underlying disease, specific drug effects(conditioning regimens) , and nutritional inadequacy as consequence of gastrointestinal dysfunction such as mucositis, vomiting , anorexia , and diarrhea, as well as possible HSCT complications such as infections and graft versus host disease (GVHD) increase the rate of malnutrition during hospital stay. Sixty adult patients are randomized to receive parenteral nutrition (total parental nutrition) (n = 30) or control (partial parenteral nutrition) (n = 30)after bone marrow transplant. Demographic data, primary admission diagnosis, concomitant disease(s) and co-administered medication(s) are recorded. Subjective global assessment (SGA), nutritional risk screening (NRI), anthropometric measurements, nitrogen balance, and laboratory data (such as albumin, prealbumin and total protein) serum electrolytes (sodium, potassium, magnesium, phosphate) at baseline (24 h after admission) and weekly thereafter during nutrition therapy , are measured and follow up 100 days after transplant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203041030N9**
Registration date: **2012-03-15, 1390/12/25**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-03-15, 1390/12/25

Registrant information

Name

Mahdi Jalili

Name of organization / entity

Hematology-Oncology & SCT Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2662

Email address

m_jalili@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Hematology Oncology and Stem Cell Transplantation Research Center

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the clinical and metabolic outcomes of pharmacotherapy based total parental nutrition support in adult patients undergoing bone marrow transplantation

Public title

Evaluation of the clinical and metabolic outcomes of pharmacotherapy based total parental nutrition support

in adult patients undergoing bone marrow transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Age ≥ 18 years; 2- $< 50\%$ oral intake due to nausea, vomiting, diarrhea, anorexia, Severe mucositis or Graft versus host disease (GVHD) and cannot use of enteral feeding; 3- albumin < 3 . Exclusion criteria: 1- Documented history of respiratory, hepatic, renal and cardiac dysfunction.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hematology Oncology and Stem Cell Transplantation Research Center

Street address

Shariati Hospital, Kargar Ave

City

Tehran

Postal code

Approval date

2012-03-01, 1390/12/11

Ethics committee reference number

1390/12/11

Health conditions studied

1

Description of health condition studied

Parental nutrition support in bone marrow

transplantation

ICD-10 code

Y84

ICD-10 code description

Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description

Length of stay (LOS)

Timepoint

Participants will be followed for the duration of hospital stay, an expected average of 3 weeks

Method of measurement

Medical record

2

Description

Incidence of acute GVHD

Timepoint

Three months after intervention

Method of measurement

Physical Examination

3

Description

Nutritional status at discharge

Timepoint

Participants will be followed for the duration of hospital stay, an expected average of 3 weeks

Method of measurement

Subjective global assessment (SGA), nutritional risk screening (NRI), anthropometric measurements, nitrogen balance, and laboratory data (such as albumin, prealbumin and total protein)

Secondary outcomes

1

Description

Days on antibiotics

Timepoint

Participants will be followed for the duration of hospital stay, an expected average of 3 weeks

Method of measurement

Medical record

2

Description

Days of fever

Timepoint

Participants will be followed for the duration of hospital stay, an expected average of 3 weeks

Method of measurement

3**Description**

Liver function tests (LFTs)

Timepoint

Participants will be followed for the duration of hospital stay, an expected average of 3 weeks

Method of measurement

Laboratory Examination

4**Description**

Rate of electrolyte disturbance

Timepoint

Participants will be followed for the duration of hospital stay, an expected average of 3 weeks

Method of measurement

Laboratory Examination

5**Description**

Rate of PN-related complications

Timepoint

Participants will be followed for the duration of hospital stay, an expected average of 3 weeks

Method of measurement

Medical record

Intervention groups**1****Description**

Intervention Group: Total parenteral nutrition (dextrose 10%, aminoacid10%, intralipid 10%, vitamins, trace element daily according to 25-35kcal/kg)

Category

Treatment - Drugs

2**Description**

Control group: Partial parenteral nutrition (aminoacid 10% daily, intralipid twice weekly, vitamins max 800 kcal/day)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hematology-Oncology & SCT Research Center

Full name of responsible person**Street address**

Shariati Hospital, Kargar Ave

City**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hematology-Oncology & SCT Research Center

Full name of responsible person

Molouk Hadjibabaie

Street address

Shariati Hospital, Kargar Ave

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hematology-Oncology & SCT Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Hematology-Oncology & SCT Research Center

Full name of responsible person

Maryam Mousavi

Position

Pharma Dr.

Other areas of specialty/work**Street address**

Shariati Hospital, Kargar Ave

City

Tehran

Postal code**Phone**

+98 21 8490 2645

Fax**Email**

kh.mousavi@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hematology-Oncology & SCT Research Center

Full name of responsible person

Molouk Hadjibabaie

Position

Associate Professor/Pharma D.

Other areas of specialty/work

Street address

Shariati Hospital, Kargar Ave.

City

Tehran

Postal code

Phone

+98 21 8490 2645

Fax

Email

hajibaba@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hematology-Oncology & SCT Research Center

Full name of responsible person

Mahdi Jalili

Position

M.D.

Other areas of specialty/work

Street address

Shariati Hospital, Kargar Ave.

City

Tehran

Postal code

Phone

+98 21 8490 2645

Fax

Email

horcbmt@sina.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty