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 parentral 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 parentral nutrition (total parental nutrition) (n = 30) or control (partial parentral 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 fallow 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
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Iran (Islamic Republic of)
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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 mocusitis or Graft versus host disease (GVHD) and cannot use of entral 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
Mediacl 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

Medical record

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 parentral nutrition (dextrose 10%, aminoacid10%, intralipid 10%, vitamins, trace element daily according to 25-35kcal/kg)
Category
Treatment - Drugs

2

Description
Control group: Partial parentral 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
Tehran

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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