

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Feasibility of outpatient autologous stem cell transplantation in patients referred to shariati hospital

Protocol summary

Summary

Total 9 patients who have been affected by malignant hematologic disorders were selected and received conditioning and autologous stem cell transplantation in hospital and next day were discharged and followed up by outpatient stem cell transplantation team. Finally we assessed the feasibility of outpatient autologous stem cell transplantation by neutrophil and platelet recovery and early mortality.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711081030N6**
Registration date: **2009-05-02, 1388/02/12**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-05-02, 1388/02/12

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

Tehran University of Medical Sciences

Expected recruitment start date

2008-05-01, 1387/02/12

Expected recruitment end date

2008-12-01, 1387/09/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Feasibility of outpatient autologous stem cell transplantation in patients referred to shariati hospital

Public title

Outpatient autologous stem cell transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Acceptance of patient. 2- Patient is in a complete remission (CR1). 3- Performance score 80-100 or 0-2. 4- No heart, liver, kidneys or lungs dysfunction. 5- The distance from the patient's home to the hospital should be no more than 60 minutes. 6- The existence of an educated care giver, with at least a diploma, who's able to be with the patient twenty-four hours a day and seven days a week. 7- The patient should have suitable living conditions at home. 8 - The patient should not be heavily treated. Exclusion criteria: 1- Patients who don't accept (to be out-patients). 2- Progressive or refractory disease. 3- A patient who has had several treatments before (heavily treated) 4- Creatinin >1.5 5- cardiac ejection fraction is less than %50 6- liver's enzymes are twice as large as normal.

Age

From **14 years** old to **45 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 9

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hematology-Oncology and SCT
Research Center

Street address

Shariati Hospital, Kargar Ave.

City

Tehran

Postal code

Approval date

2008-10-18, 1387/07/27

Ethics committee reference number

418/87/673/الف

Health conditions studied

1

Description of health condition studied

Outpatient autologous stem cell transplantation

ICD-10 code

Z76.1

ICD-10 code description

Health supervision and care of founding

Primary outcomes

1

Description

WBC recovery

Timepoint

One month after transplantation

Method of measurement

Absolute Neutrophil Count $\geq 0.5 \times 10^9 / L$

2

Description

Platelet recovery

Timepoint

One month after transplantation

Method of measurement

Platelet $\geq 20 \times 10^9 / L$

Secondary outcomes

1

Description

Early mortality

Timepoint

One year after transplantation

Method of measurement

Survival monitoring

Intervention groups

1

Description

Autologous stem cell transplantation as outpatient

Category

Other

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yonesian

Street address

Enghelab Sq.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

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

Akram Karimi

Position

Coresponder / M.D.

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

Shariati Hospital, Kargar Ave.

City

Tehran

Postal code**Phone**

+98 21 8490 2668

Fax**Email**

horcbmt@sina.tums.ac.ir

Web page address<http://horcsct.tums.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hematology-Oncology and SCT Research Center

Full name of responsible person

Aboulghasem Allahyari

Position

Principal Investigator / Fellowship

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

Kargar Ave. Shariati Hospital

City

Tehran

Postal code

14114

Phone

+98 21 8490 2635

Fax**Email**

horcbmt@sina.tums.ac.ir

Web page address<http://horcsct.tums.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

Hematology-Oncology and SCT Research Center

Full name of responsible person

Mahdi Jalili

Position

Clinical Trials Unit secretary / MD

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

Kargar Ave. Shariati Hospital

City

Tehran

Postal code

14114

Phone

+98 21 8490 2668

Fax**Email**

horcsct@yahoo.com

Web page address<http://horcsct.tums.ac.ir>**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*