Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of autologous bone marrow stem cells transfusion in treatment of cirrhotic, in decompensated cirrhotic patients

Protocol summary

Summary

Objectives: To evaluate the effect of bone marrow stem cell injection in the peripheral vein on the treatment of decompensated cirrhotic patients. Design: Interventional, randomized, non-blinded design Target sample size: Twenty patients suffering from liver cirrhosis, waiting for liver ransplant. Major inclusion criteria: Age range of 18 to 60 years; Having cirrhosis, based on clinical symptoms and laboratory, endoscopic and radiological findings; Being a candidate for liver transplant. Major exclusion criteria: Concurrent diseases such as heart, kidney, and pulmonary conditions; Presence of a hepatic mass indicating hepatocellular carcinoma, according to radiological findings. Intervention: Stem cells (120-200 CC) are injected in patients with liver cirrhosis, using special filters to collect fat particles, possible clots and other particles during one hour. Setting and conduct: Bone marrow aspiration is generally performed to obtain bone marrow cells. After collecting 120 cc of bone marrow cells, the number and percentage of nucleated cells are determined by a laboratory expert. Aspiration continues until the total number of nucleated cells reaches the minimum acceptable threshold of about 10 (9)*1. Then, the total volume of aspirated bone marrow cells is injected in patients with liver cirrhosis, using special filters to collect fat particles, possible clots, and other particles over one hour. Main outcome measures: Laboratory tests (albumin, hemoglobin and blood clotting tests) were carried out once a week after the intervention for a period of two week by blood test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091919217N1**
Registration date: **2014-10-23, 1393/08/01**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2014-10-23, 1393/08/01

Registrant information

Name
Homeira Ommati
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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omatih9111@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2015-06-01, 1394/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of autologous bone marrow stem cells transfusion in treatment of cirrhotic, in decompensated cirrhotic patients

Public title

Treatment of cirrhotic of liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age range of 18 to 60 years; Having cirrhosis, based on clinical symptoms and laboratory, endoscopic and radiological findings; Being a candidate for liver transplant. Exclusion criteria: Concurrent diseases such as heart, kidney, and pulmonary conditions; Presence of a hepatic mass indicating hepatocellular carcinoma, according to radiological findings; Extrahepatic malignancies; Moderate to severe hepatic encephalopathy; HIV positive; Presence of malignancies; Activated hepatic vein thrombosis, spleen and portal venous; Concurrent extrahepatic infections; Active venous bleeding; History of alcohol consumption; Lack of patient's consent

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

20 People, via lottery, were selected between patients who were candidate to waiting for Liver Transplant

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad, Iran

City

Mashhad

Postal code

Approval date

2014-06-22, 1393/04/01

Ethics committee reference number

920377

Health conditions studied

1

Description of health condition studied

Cirrhotic of liver

ICD-10 code

K76.1

ICD-10 code description

Chronic passive congestion of liver

Primary outcomes

1

Description

MELD score

Timepoint

Every week after the intervention for two weeks

Method of measurement

Calculating by algorithm formula.

2

Description

Laboratory tests (albumin, hemoglobin and blood clotting tests)

Timepoint

once a week after the intervention for a period of two week

Method of measurement

Blood test

3

Description

Child score

Timepoint

Every week after the intervention for two weeks

Method of measurement

Calculating by algorithm formula.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Stem cells (120-200 CC) are injected in patients with liver cirrhosis, using special filters to collect fat particles, possible clots and other particles during one hour.

Category

Treatment - Other

2

Description

Control group: Patients with liver cirrhosis, not receiving

stem cells, were allocated to the control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Homeira Omati

Street address

Imam Reza hospital, Imam Reza square, Mashhad, Iran

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Saeed Eslami

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Homeira Omati

Position

Resident

Other areas of specialty/work

Street address

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Person responsible for updating data

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Name of organization / entity

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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