

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Cell therapy using human-derived placental-derived mesenchymal stem cells in patients with Acute liver failure: clinical trial phase I

Protocol summary

Study aim

Determination of Safety and Feasibility of Cell Therapy Using Human-Derived Mesenchymal Stem Cells in Improving Patients with Acute Liver Failure

Design

One group of 5 patients with uncontrolled, clinical trial phase 1

Settings and conduct

Intravenous injection of mesenchymal stem cells in Shariati hospital and Imam Khomeini hospital in Tehran

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. ALF: The occurrence of hepatic encephalopathy is less than 8 weeks after the onset of jaundice in a disease that has no history of known liver disease. 2. All patients with ALF or ACLF at the time of the study admitted to Shariati Hospital and Imam Khomeini Hospital. Exclusion criteria: 1. Patient dissatisfaction 2. Pregnant patient 3. Age less than 17 years 4. A patient with known active malignancy

Intervention groups

Placenta-derived mesenchymal stem cells is about 1×10⁶ MSC / Kg by intravenous injection twice injection in one patient

Main outcome variables

the level of consciousness Laboratory tests : Coagulation tests (PT, INR), Aminotransferase, Ammoniac level, Bilirubin, Cell count, Lactate, Creatinine / Bun, Na / K, Albumin level, Blood Sugar

General information

Reason for update

Acronym

P-MSCs

IRCT registration information

IRCT registration number: **IRCT20190717044241N1**

Registration date: **2020-02-15, 1398/11/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-15, 1398/11/26**

Update count: **0**

Registration date

2020-02-15, 1398/11/26

Registrant information

Name

Mahshid Saleh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7736 5353

Email address

mahshid_saleh@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cell therapy using human-derived placental-derived mesenchymal stem cells in patients with Acute liver failure: clinical trial phase I

Public title

Infusion of human-derived placental-derived mesenchymal stem cells in patients with acute liver failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ALF: The occurrence of hepatic encephalopathy is less than 8 weeks after the onset of jaundice in a disease that does not have a history of known liver disease. All patients with ALF or ACLF are admitted to hospital at Shariati Hospital and Imam Khomeini Hospital.

Exclusion criteria:

Patient dissatisfaction Pregnant patient Age less than 17 years Patient with known active malignancy

Age

From **17 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **5**

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

Iran National committee for Ethics in Biomedical research

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

.....

Approval date

2019-12-25, 1398/10/04

Ethics committee reference number

IR.TUMS.VCR.REC.1398.740

Health conditions studied

1

Description of health condition studied

Acute liver failure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Type and amount of observed side effects due to placental mesenchymal stem cells in patients with Acute Liver Failure in order to safety assessment for this intervention.

Timepoint

At 24, 48, 72 hours and one month post cell transplantation

Method of measurement

General physical assessments and laboratory tests like blood, serum, and urine analysis.

2

Description

Severity of clinical scores, Consciousness Test

Timepoint

At 24, 48, 72 hours and one month post cell transplantation

Method of measurement

clinical observation by Gastroenterologist

3

Description

assessment of Liver function

Timepoint

At 24, 48, 72 hours and one month post cell transplantation

Method of measurement

PT, INR, ALT, AST, CBC

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with acute liver failure who are transplanted with placenta-derived mesenchymal stem cells that are injected $1-1.5 \times 10^6$ Via (IV) intravenous injection.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital & Imam Khomeini Hospital

Full name of responsible person

Dr Mahdi Mohamad Zadeh

Street address

Tehran Province, Tehran, District 6, Jalal Al Ahmad Highway

City

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Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraian

Street address

Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital

City

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Province

Tehran

Postal code

۱۱۳۶۷۶۹۱۱

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msahrai@sina.tums.ac.ir

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

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

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

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mahshid Saleh

Position

دانشجو دکترا

Latest degree

Master

Other areas of specialty/work

Cell Therapy

Street address

Tehran Province, Tehran, Eastern side of Tehran University, Italy St, No. 88

City

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Javad Verdi - Dr Mehdi Mohammadnejad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Cell Therapy

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

مهشید صالح

Position

دانشجو دکترا

Latest degree

Master

Other areas of specialty/work

Cell Therapy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available