

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial of the treatment of Erectile Dysfunction (ED) by using of adipose derived mesenchymal stem cells (MSCs)

Protocol summary

Study aim

A clinical trial of the treatment of Erectile Dysfunction (ED) by using of adipose derived mesenchymal stem cells (MSCs)

Design

A clinical trial with two groups of patients: parallel, therapeutic, simple random, single blind (researcher). 100 patients referred to Sinai Hospital.

Settings and conduct

100 patients at Sina Hospital. blanced block randomization, single blind(researcher). Patients are divided into two groups. After completing the written consent, In one group, 5 million adipose-derived mesenchymal stem cells are injected in three times, and in the other group, 10 million cells are injected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mental health/Do not take psychiatric drugs/Age range 18-70 years/No possibility of damage to the main pelvic arteries/Reluctance to change the penis prosthesis/Tendency to perform stem cell injection therapy Exclusion criteria: Patients with cardiovascular disease/Underlying diseases Psychiatric problems or addiction/Failure to follow the patient at the appointed times/Deactivation of sexual life/neurologic or hormonal Erectile dysfunction/lack of sexual interest

Intervention groups

Intervention Group1: Adipose is removed from a specific area of the patient's thigh or abdomen with a simple surgery, then the patient's adipose derived mesenchymal stem cells are separated and processed under appropriate conditions and injected into the patient (5 million cells in three injections). Intervention Group2: Adipose is removed from a specific area of the patient's thigh or abdomen with a simple surgery, then the patient's adipose derived mesenchymal stem cells are separated and processed under appropriate conditions and injected into the patient (10 million cells in three injections).

Main outcome variables

Improving the quality of patients' erections, Increase patient satisfaction, Patients' desire for sex, Effectiveness time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043991N11**

Registration date: **2020-11-27, 1399/09/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-27, 1399/09/07**

Update count: **0**

Registration date

2020-11-27, 1399/09/07

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8560

Email address

mkaghamir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2021-08-11, 1400/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A clinical trial of the treatment of Erectile Dysfunction (ED) by using of adipose derived mesenchymal stem cells (MSCs)

Public title
Evaluation of Mesenchymal Stem Cell transplantation (MSCS) in the treatment of Erectile Dysfunction (ED)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Mental Health Do not take psychiatric drugs Age range 18-70 years No possibility of damage to the main pelvic arteries Reluctance to change the penis prosthesis Tendency to perform stem cell injection therapy
Exclusion criteria:
Patients with Cardiovascular disease Underlying diseases Psychiatric problems or Addiction Failure to follow the patient at the appointed times Deactivation of Sexual Life Neurologic or Hormonal Erectile Dysfunction Lack of Sexual Interest

Age
From **18 years** old to **70 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The present study is a single-blind randomized clinical trial. For randomization, the blanced block randomization method is used to generate four blocks. Intervention group A and control group B have been determined. According to the randomization method, we expect the two groups to differ by a maximum of 2 people in terms of the number of people assigned. After the methodologist prepares the randomization sequence using the sealdenvelop online site, the generated sequence will be made available to a technician outside the research team. Quadruple blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected and the type of patient group is informed to the research team through a trained technician. The patient is placed in (5 million cells in three injections) or (10 million cells in three injections) group based on the randomly selected envelope.

Blinding (investigator's opinion)
Single blinded

Blinding description
The researcher has no information about the surgical

procedure and the design. Surgery is performed by various surgeons during the week, and finally, the coded results are delivered to the researcher.

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee for Research in Tehran University of Medical Sciences
Street address
Room 604, Sixth Floor, medical University Tehran, Central Staff Building, Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2020-09-10, 1399/06/20
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.438

Health conditions studied

1

Description of health condition studied
Erectile Dysfunction
ICD-10 code
N52.9
ICD-10 code description
Male erectile dysfunction, unspecified

Primary outcomes

1

Description
Improve erectile quality

Timepoint
One month, two months, three months, six months and one year after adipose derived mesenchymal stem cells injection

Method of measurement
Record of Peak systolic velocity (PSV) and end diastolic velocity (EDV) and complete the International Index of Erectile Function (IIEF-5) questionnaire and perform color Doppler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Adipose is removed from a specific area of the patient's thigh or abdomen with a simple surgery, then the patient's adipose derived mesenchymal stem cells are separated and processed under appropriate conditions and injected into the patient (5 million cells in three injections)(One month, two months and three months after the intervention, the same number of cells are injected into the patient).

Category

Treatment - Surgery

2

Description

Intervention group: Adipose is removed from a specific area of the patient's thigh or abdomen with a simple surgery, then the patient's adipose derived mesenchymal stem cells are separated and processed under appropriate conditions and injected into the patient (10 million cells in three injections)(One month, two months and three months after the intervention, the same number of cells are injected into the patient).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Seyed Mohammad Kazem Aghamir Mohammadali

Street address

Urology Research Center, Sina Hospital, Imam Khomeini St., Tehran, Iran.

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Tehran

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1136746911

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Email

mkaghamir@tums.ac.ir

Web page address

<http://sinahospital.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

Sixth Floor, Central University, Quds Ave., Keshavarz Boulevard, Tehran.

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Web page address

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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

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

Dr Akram Mirzaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Molecular Medicine

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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 Mohammad Kazem Aghamir
Position
Head of Urology Research Center
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Akram Mirzaei
Position
Researcher
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

demographic information anonymously

When the data will become available and for how long

one year after publication

To whom data/document is available

Researchers working in academia, physicians, surgeons and hospitals

Under which criteria data/document could be used

Any analysis can be done with the consent of the main researcher

From where data/document is obtainable

Sina Hospital, Urology Research Center, Head of Urology Research Center: Dr. Seyed Mohammad Kazem Aghamir
00982166348560

What processes are involved for a request to access data/document

After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.

Comments

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