Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial of the evaluation of the effect of intracavernous stem cell injection on the treatment of erectile dysfunction compared to control group in diabetic patients

Protocol summary

Study aim

Evaluation of the Effect of Intracavernous Stem Cell Injection on the Treatment of Erectile Dysfunction in Diabetic Patients Referring to Kerman Diabetes Clinic in 2019

Design

Clinical trial with control group, with parallel groups, single blind, block randomization

Settings and conduct

In the intervention group, with local anesthesia, a tissue sample of about half a centimeter diameter without the need for suturing from the oral mucosa of each person was taken and immediately sent to the center of the stem cells of the Kerman University of Medical Sciences. In the intervention group, a 1 cc stem cell is injected into each corpus cavernosome, and in the normal control group, 1 cc is injected into both corpus cavernosomes. Patients are not aware of the type of injectable(single blind). Patients are followed up with International Index of Erectile Function (IIEF5) questionnaire and Doppler doppler sonography, Fasting Blood Sugar (FBS) and Glycated hemoglobin (HBA1C) within three months and six months after injection. In addition, morning erection is recorded by patients every day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetes, sexual dysfunction, BMI 20-25 and Ages: 55-75 years. Exclusion criteria: Laboratory disorders (low testosterone and high prolactin and high fasting blood glucose and impaired lipids and ...) Heart disease Other diseases leading to erectile dysfunction

Intervention groups

In the intervention group, a tissue sample is taken from the oral mucosa of each person and sent to the center of the stem cell. The cells collected in the intervention group are injected into each corpus cavernosome of one cent. In the normal control group,1 cc of saline is injected into both corpus cavernosomes.

Main outcome variables

Improving erectile function in patients Complications of injection (pain, swelling and ecchymosis)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190517043609N1**
Registration date: **2020-01-25, 1398/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-25, 1398/11/05**
Update count: **0**

Registration date

2020-01-25, 1398/11/05

Registrant information

Name

mohammadali bagherinasabsarab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3222 1600

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ma_bagherinasab_md@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the evaluation of the effect of intracavernous stem cell injection on the treatment of erectile dysfunction compared to control group in diabetic patients

Public title

Evaluation of the effect of intracavernous stem cell injection on the treatment of erectile dysfunction in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Erectal dysfunction Diabetes Ages: 55-75 years

Exclusion criteria:

Hypertension Hyperlipidemia Obesity Low testosterone High prolactin Hypothyroidism Hyperthyroidism Impaired Luteinizing Hormone (LH) Impaired Follicle Stimulating Hormone (FSH)

Age

From **55 years** old to **75 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method is used. Thus, of the 4 blocks, each block consisting of 2 intervention groups and 2 control groups, with the aim of progressing smoothly over the time of the groups, and this method continued until the sample size was completed 20 (including 10 Intervention group and 10 control group or 5 blocks of 4).

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the primary researcher (physician and data collector) is aware of the type of injectable material, but patients are unaware of the type of injectable material and are kept blind. Patients were divided into two groups of 10 intervention and control groups who were injected randomized with stem cell or normal saline.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Havaniroz Street ,Ghadir Street

City

Kerman

Province

Kerman

Postal code

7618113908

Approval date

2019-10-13, 1398/07/21

Ethics committee reference number

115.IR.KMU.AH.REC.1398

Health conditions studied

1

Description of health condition studied

Erectile dysfunction

ICD-10 code

N52

ICD-10 code description

Male erectile dysfunction

Primary outcomes

1

Description

Erectile function

Timepoint

3 and 6 months after the injection

Method of measurement

Questionnaire IIEF5 (International Index of Erectile Dysfunction Inventory) and Patient Statement and Color Doppler Sonography

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: In the intervention group with local anesthesia, a tissue sample of about half a centimeter diameter without any need for suture was taken from each patient's oral mucosa and inserted into a solution of phosphate buffer containing antibiotics and amphotripsin (Exir Nano Sina co.) and immediately sent to the University's Stem Cell Center. Mucosal tissue transmitted 3 times with antibiotic buffered phosphate buffer and amphotripsin, divided into small parts under sterile conditions and at 4 ° C for 24 hours, adjacent to DMEM (Dulbeccos Modified Eagle Medium) (Neda Shimi Co.) medium containing 4 mg / mL of dysphasic enzyme and 3 mg / mL collagenase type 1 is placed. After 24 hours, the enzymum is slowly released and placed in a DMEM medium containing 15% FBS and 1% antibiotic (penicillin / streptomycin) (Exir Nano Sina co.) in a CO2 incubator (5%) with a humidity of 95% and a temperature of 37 °.After sticking and growing cells, which lasts for at least about 10 days, the adherent cells of the adipose trypsin enzyme are cultured again in the T25 flask after separation. Finally, the cells were examined for stem cell markers and purity by fluocytometric method and if th purity was more than 95%, the cells collected to be injected into the patient should be kept in the physician. After taking the required amount of stem cells (60-50 million), the sample is sent to the Freeze room to the urological room and after melting with normal saline 0.9% diluted (up to 2 cc), into the intervention group in each corpus cavernosome is injected 1 cc. Then all patients in the intervention group follow by the International Index of Erectile Function (IIEF5) questionnaire and Doppler Sonography, Fasting Blood Sugar (FBS), and Glycated Hemoglobin (HBA1C) within three months and six months after injection. In addition, morning erection is recorded by patients every day.

Category

Treatment - Drugs

2

Description

Control group: In control group, 1 cc normal saline is injected in each Corpus cavernosum .Then all patients in the control group follow by the IIEF5 questionnaire and Doppler Sonography, FBS, and HBA1C within three months and six months after injection. In addition, morning erection is recorded by patients every day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Kerman Diabetes

Full name of responsible person

Mahbobe Mirzaie

Street address

Qaraney street, Bahonar hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mahbobe Mirzaie

Position

Assistant Professor

Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
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Student
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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