

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Intra-testicular Injection of Autologous Adipose Derived Mesenchymal Stem Cell (ADMSC) in Non-obstructive Azoospermia Patients: Clinical Trial, Phase I, Non-Randomized

Protocol summary

Study aim

Aim 1 (Primary End Point include): Safety and Tolerability: [Time Frame: 6 months] Incidence and severity of Adverse events and Severe Adverse Events Vital signs Physical examination Clinical chemistries, hematology, and urinalysis Safety and tolerability assessments will be done 2 weeks, 1,2,3,4,5 and 6 months after the cell injection. Aim 2: (Secondary End Point include): Efficacy [Time Frame: 6 months] Sperm retrieval rate (SRR) [Time Frame: 6 months] By Semen analysis every month until any sperm is found in the semen. If no sperm is found at the end of the 3rd month, testicular sperm extraction (TESE/TESA) will be performed and the tissue will be used for histological assessment. Sperm density Sperm motility Total serum Testosterone level (TH) Number spermatogonia Number of spermatocytes Total serum estradiol level Total serum follicle stimulating hormone level (FSH) Total serum luteinizing hormone level (LH) Inhibin B hormone Prolactin Improvement in sexual function will be assessed using a questionnaire

Design

non randomized non blinded phase I clinical trial

Settings and conduct

Field: Cell therapy Place: JSC Astana Medical University, Astana, Kazakhstan Method: Autologous intratesticular MSC transplantation

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20-50 years infertile males seeking fertility treatment with confirmed diagnosis of Non-obstructive azoospermia (NOA) and all items were explained in the previous page. Exclusion Criteria: Treated with drug which could improve sperm count and quality one month before observation, otherwise, they should have an elution for 1 month before the study and all items were explained in the previous page.

Intervention groups

10 patients who are NOA based on the eligibility criteria and after obtaining informed consent will be treated with mesenchymal stem cells.

Main outcome variables

NOA treatment with MSC

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190519043634N1**

Registration date: **2019-08-05, 1398/05/14**

Registration timing: **prospective**

Last update: **2019-08-05, 1398/05/14**

Update count: **0**

Registration date

2019-08-05, 1398/05/14

Registrant information

Name

Amin Tamadon

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3335 0406

Email address

tamadon@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

2019-12-22, 1398/10/01

Actual recruitment end date

2021-12-22, 1400/10/01

Trial completion date

2022-02-20, 1400/12/01

Scientific title

Intra-testicular Injection of Autologous Adipose Derived Mesenchymal Stem Cell (ADMSC) in Non-obstructive Azoospermia Patients: Clinical Trial, Phase I, Non-Randomized

Public title

Azoospermia Treatment with Mesenchymal Stem Cell

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

20-50 years infertile males seeking fertility treatment with confirmed diagnosis of Non-obstructive azoospermia (NOA). Patients with confirmed diagnostic of Non-obstructive azoospermia based on 2 negative spermogram with centrifugation (three months in between). Patients without sperm cells at semen analysis. Body mass index (BMI) lower than 35. Negative testicular sperm extraction (TESE): Failure of detecting spermatozoid TESE.

Exclusion criteria:

Treated with drug which could improve sperm count and quality one month before observation, otherwise, they should have an elution for 1 month before the study. Previous surgical history in Testis. Absent or surgical removed testes Infectious genital diseases. Gram-positive bacteria, Chlamydia Trachomatis, Ureaplasma Urealyticum, or Mycoplasma Hominis were detected in their semen. Anatomical abnormalities of the genital tract Patients with grade 2 or 3 varicocele, persistent after cure of the varicocele. Current or history of testicular tumor detected or testicular cancer or history of any other cancer. Obstructive azoospermia (FSH <7.6 IU/mL plus testicle longitudinally axis >4.6 cm or bilateral absence of vas deferens or surgical history of vasectomy). Hypogonadotropic hypogonadism (LH <2 IU/mL and Follicle Stimulating Hormone (FSH) <1 IU/mL). Patient with Klinefelter or karyotype abnormalities Seminal white blood cell concentration more than 10 million per ml Use of chemotherapy, testosterone, or anti-androgen in the last two years. Partner >40 years or female factor infertility associated. Addicted to drug, tobacco, or alcohol. Under treatment of gonadotropin, anabolic steroid, chemotherapeutic drugs, or nonsteroidal anti-inflammatory drugs. Combined with cardiovascular, liver, kidney, or hematopoietic system severe primary disease, or mental disease. Had heat, chemicals, radioactive material, or toxic contact history within a year. Presence of genetic disorders: abnormal karyotypes and Chromosomal aberration (e.g. Y microdeletion, trisomy.... First TESE conducted under hormonal treatment (Clomifene, Tamoxifen, gonadotrophins or anti-aromatase) Receiving a treatment known to alter male fertility (see RCP of the treatment, colchicine, methotrexate and...) in the 6

months before inclusion. Receiving treatment know to modify the gonadotroph axis activity (FSH, TESTO, DHT, HCG...) Persistent bilateral abdominal cryptorchidism or history of cryptorchidism Patient unable to understand the purpose of the trial or refusing to follow treatment and post-treatment instructions Participation to another trial that would interfere with this trial

AgeFrom **20 years** old to **50 years** old**Gender**

Male

Phase

1

Groups that have been masked

No information

Sample sizeTarget sample size: **10**Actual sample size reached: **30****Randomization (investigator's opinion)**

Not randomized

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**

Medical University of Astana

Street address

Beibitshilik Street 49/A, Nur-Sultan 010000, Kazakhstan

City

Nur-Sultan

Postal code

010000

Approval date

2019-05-22, 1398/03/01

Ethics committee reference number

protocol number 7

Health conditions studied**1****Description of health condition studied**

Non-obstructive Azoospermia

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Induction of spermatogenesis

Timepoint

at 2 week, 1, 2, 3, 4, 5 and 6 post injection day

Method of measurement

Hematological, biochemical, Retrieval sperm rate ,Sperm density, Sperm motility, Total serum testosterone level (TH), Number spermatogonia, Number of spermatocytes, Total serum estradiol level, Total serum follicle stimulating hormone level (FSH), Total serum luteinizing hormone level (LH), Inhibin B hormone, Prolactin, sexual function

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cell therapy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical University of Astana

Full name of responsible person

Ulanbek Zhanbyrbekuly

Street address

Beibitshilik Street 49/A, Nur-Sultan 010000,
Kazakhstan

City

Nur-Sultan

Postal code

010000

Phone

+7 7172 53 94 24

Email

ulanbek.amu@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Center of Science and Technology Evaluation

Full name of responsible person

Ulanbek Zhanbyrbekuly

Street address

Bogenbai Batyr Street 221

City

Almaty

Postal code

050026

Phone

+7 727 378 0509

Email

info@ncste.kz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

National Center of Science and Technology Evaluation

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

Boushehr University of Medical Sciences

Full name of responsible person

Amin Tamadon

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Moalem Square, Parastar Street, Persian Gulf
Biotechnology Research Center

City

Boushehr

Province

Boushehr

Postal code

7514763448

Phone

+98 77 3332 8724

Email

amintamaddon@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Amin Tamadon

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Moalem Square, Parastar Street, Persian Gulf
Biotechnology Research Center

City

Boushehr

Province

Boushehr

Postal code

7514763448

Phone

+98 77 3332 8724

Fax

+98 77 3332 8724

Email

amintamaddon@yahoo.com

Phone

+98 35 3824 7085

Fax

+98 35 3824 7087

Email

mehrarezoo@gamil.com

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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all collected de-identified IPD

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

For use in meta-analysis studies or systematic review articles

From where data/document is obtainable

Corresponding with the person responsible for scientific inquiries, Dr. Amin Tamadnan: Moalem Square, Parastar Street, Persian Gulf Biotechnology Research Center, amintamaddon@yahoo.com

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

An official letter with the header of the university or research institute by email or fax to the person responsible for scientific inquiries

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Arezoo

Position

Lab supervisor

Latest degree

Master

Other areas of specialty/work

Medical Biology

Street address

Yazd Science Research Institute, Bouali Ave., Timsar
Fallahi Avenue, Safayehi

City

Yazd

Province

Yazd

Postal code

8916877391