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

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Email address

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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
Age
From **20 years** old to **50 years** old
Gender
Male

Phase
1
Groups that have been masked
No information
Sample size
Target 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
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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
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050026
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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
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Latest degree
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Other areas of specialty/work
Medical Biology
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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
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