

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The effectiveness of injecting mesenchymal cell-derived exosomes into cesarean scar in women with repeat caesarean section at the time of laparoscopic cesarean niche repair.

Protocol summary

Study aim

The effectiveness of exosomes into cesarean scar at the time of laparoscopic niche repair.

Design

This is a randomized triple-blind ,placebo control, phase 3 clinical trial involving a total of 60 patients; 30 patients in the case group allocated to 30 patients in the control group. For randomization, 30 "A" labels and 30 "B" labels covered in envelopes are placed in a box. For each patient an envelope is drawn out of the box. The physician, the patients, and the data analyst are be blinded to groups assignments.

Settings and conduct

This randomized, triple-blinded, placebo controlled ,clinical trial with a case group (exosomes injection) control group (sterile water injection) will be conducted at the operation room of Yas Hospital. Random allocation will be used regarding case and control groups. The patients, physician, and data analysts will be blinded to the group assignments.

Participants/Inclusion and exclusion criteria

Patients with niche who are candidate for laparoscopic repair. Inclusion criteria: Patients with niche and infertility, Patients with niche and pelvic pain, Patients with niche and AUB, Patients with niche and recurrent implantation failure Exclusion criteria: Patients who are not candidate for laparoscopic surgery

Intervention groups

This randomized, triple-blinded, placebo controlled ,clinical trial with a case group (exosomes injection) control group (sterile water injection) will be conducted at the operation room of Yas Hospital. Random allocation will be used regarding case and control groups. The patients, physician, and data analysts will be blinded to the group assignments.

Main outcome variables

Evaluation of niche by transvaginal sonogram.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002576N36**

Registration date: **2024-02-24, 1402/12/05**

Registration timing: **prospective**

Last update: **2024-02-24, 1402/12/05**

Update count: **0**

Registration date

2024-02-24, 1402/12/05

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-20, 1403/01/01

Expected recruitment end date

2025-03-21, 1404/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of injecting mesenchymal cell-derived exosomes into cesarean scar in women with repeat caesarean section at the time of laparoscopic cesarean niche repair.

Public title

Evaluation exosomes on niche

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with niche and infertility Patients with niche and pelvic pain Patients with niche and AUB Patients with niche and recurrent implantation failure

Exclusion criteria:

Patients who are not candidate for laparoscopic surgery

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule: At first, on special unmarked papers, 30 A letters and 30 B letters are written. Then all(60) are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly without replacement. Based on the letter written on it, the intended intervention is performed on the patient. In addition, interventions A (exosome injection) or B (sterile water injection) are determined by lottery.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients and physician are blinded regarding the groups ,and analyzer only sees the codes in data sheet and is blinded regarding.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tehran University of medical sciences

Street address

Sixth floor of central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1597815978

Approval date

2024-02-20, 1402/12/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.6

Health conditions studied

1

Description of health condition studied

Laparoscopic repair of niche

ICD-10 code

O34.21

ICD-10 code description

Maternal care for scar from previous cesarean delivery

Primary outcomes

1

Description

Evaluation of niche by transvaginal sonogram

Timepoint

Six weeks after surgery

Method of measurement

Transvaginal sonogram

2

Description

AUB, pelvic pain

Timepoint

Sixth weeks after surgery

Method of measurement

Patient History

3

Description

Infertility

Timepoint

Two months after surgery

Method of measurement

BhCG blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: During laparoscopic repair cesarean scar will be resected then uterine incision will be repaired by vicryl 1and exosomes injected.

Category

Treatment - Surgery

2

Description

Control group: During laparoscopy ,uterine incision will be resected and repaired by vicryl 1and strile water injected in the site of scar.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Fatemeh Davari Tanha

Street address

Yas hospital, North Nejatollahi Avenue, Villa Street

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Akbari sari

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Sixth floor of central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd

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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

Fatemeh Davari Tanha

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

SPSS file

When the data will become available and for how long

After publishing article

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Related scientific analysis

From where data/document is obtainable

Mail to Fatedavtanha@gmail.com

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

Formal request

Comments