

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Cell therapy with use of mesenchymal stem cells in infertile women with Thin Endometrium

Protocol summary

Study aim

Cell therapy with use of mesenchymal stem cells in infertile women with Thin Endometrium

Design

Phase 1 clinical trial without control group, on 10 patients

Settings and conduct

In this study, infertile women will be selected according to the inclusion and exclusion criteria. Patients will be signed the informed consent. Patients will be received three injections of umbilical cord mesenchymal stem cells and their secretom with the intervals of one month.

Participants/Inclusion and exclusion criteria

Infertile women with thin endometrium, Endometrium thickness less than 7 mm, Patients who have ineffective routine treatment; Patients who have other uterine diseases, Patients who have systemic disorders such as diabetes.

Intervention groups

Patients will be received mesenchymal stem cells and their secretome

Main outcome variables

Endometrium thickness, Implantation rate, live birth rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057500N1**

Registration date: **2023-04-03, 1402/01/14**

Registration timing: **prospective**

Last update: **2023-04-03, 1402/01/14**

Update count: **0**

Registration date

2023-04-03, 1402/01/14

Registrant information

Name

Saeedeh Torabi Goudarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4305 2000

Email address

s-torabig@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cell therapy with use of mesenchymal stem cells in infertile women with Thin Endometrium

Public title

Cell therapy with use of mesenchymal stem cells in infertile women with Thin Endometrium

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women with thin endometrium patient with thin endometrium for whom drugs and other treatments were ineffective Endometrial thickness less than 7 mm Embryo transfer is cancelled because of thin endometrium Age between 20 and 44 years HBsAg negative, HCV negative,

HIV negative, CMV negative
Exclusion criteria:
 Abnormal karyotype Contraindications to hormone replacement therapy Systemic diseases such as hypertension, diabetes Other uterine diseases including uterine malformations, large myoma, endometrial tuberculosis, endometriosis Autoimmune diseases such as rheumatoid arthritis, lupus Unable to adhere to the follow-up

Age
 From **20 years** old to **44 years** old

Gender
 Female

Phase
 1

Groups that have been masked
No information

Sample size
 Target sample size: **10**

Randomization (investigator's opinion)
 N/A

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

Research Ethics Committees of Research Institute for Oncology, Hematology and Cell Therapy - Tehran

Street address

Shariati Hospital, Kargar Shomali Ave, Tehran, 14117-13135 I.R.Iran

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2023-02-05, 1401/11/16

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1401.033

Health conditions studied

1

Description of health condition studied

Female infertility with thin endometrium

ICD-10 code

N97.2

ICD-10 code description

Female infertility of uterine origin

Primary outcomes

1

Description

Endometrium thickness

Timepoint

Before the intervention and 1, 2 and 3 months after the first intervention

Method of measurement

Vaginal sonography

Secondary outcomes

1

Description

The effect of cell therapy on fertility rate of patients

Timepoint

15 days after embryo transfer

Method of measurement

Using sonography and serum beta-human chorionic gonadotropin (β -hCG) level assessment by enzyme-linked immunosorbent assay (ELISA) or chemiluminescence

Intervention groups

1

Description

Intervention group: patients will be received three injections of Umbilical cord-derived Mesenchymal Stem Cells and their secretome.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Fertility Research Center

Full name of responsible person

Saeedeh Torabi Goudarzi

Street address

Valiasr Fertility Research Center, Imam Khomeini Hospital, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6658 1616
Fax
Email
vrhrc@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Vice President of Research and Technology, 6th Floor,
Central Organization of Tehran University of Medical
Sciences, Corner of Qods St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Email
vcr@tums.ac.ir

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
Saeedeh Torabi Goudarzi
Position
PhD candidate
Latest degree
Master
Other areas of specialty/work

Applied Cell Sciences

Street address

No. 88, School of Advanced Technologies in Medicine,
Italia st, Keshavarz blv.

City

Tehran

Province

Tehran

Postal code

1417755469

Phone

+98 21 4305 2000

Email

s-torabig@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nasim Vosoughi _ Mehdi Yousefi _ Saeedeh Torabi
Goudarzi

Position

Associate Professor _ Associate Professor _ PhD
candidate

Latest degree

Ph.D.

Other areas of specialty/work

Cell Therapy _ Immunology _ Applied Cell Sciences

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Saeedeh Torabi Goudarzi

Position

PhD candidate

Latest degree

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Email
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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