Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparing the depth of embryo transfer and its effect on the outcomes of frozen embryo transfer cycles: a double-blind RCT

Protocol summary

Study aim
Comparing the depth of embryo transfer and its effect on the outcomes of frozen embryo transfer cycles

Design
204 women applying for the transfer of gynecological freeze, referring to Hazrat Zainab infertility treatment center and meeting the entry requirements, will be included in the study; All patients, with or without suppuration, receive oral estradiol at a dose of 4-6 mg from the second or third day of the menstrual cycle, and after the transvaginal ultrasound, the thickness of the endometrium is good and sufficient for embryo transfer, they are candidates for embryo transfer; After homogenization of patients in terms of demographic and clinical characteristics, people will be divided into three groups by random allocation of blocks. In this study, all patients are blinded. In the first group, embryo transfer at a depth of 0.5 to 1.5 cm, in the second group, embryo transfer at a depth of 1.5 to 2.5 cm, and in the third group, embryo transfer at a depth of 2.5 to 3.5 cm. (embryos are transferred in the cleavage or blastocyst stage) will take placeFinally, after 2 weeks, the result of chemical pregnancy will be checked using the B-HCG test, and after 6 weeks, the result of clinical pregnancy

Settings and conduct
infertility treatment center of Zainab Hospital in Shiraz

Participants/Inclusion and exclusion criteria
Patients aged 20 to 45 years; Patients with at least two good quality embryos for transfer; Patients with healthy uterine cavity confirmed by hysterosalpingography and hysteroscopy or saline ultrasound.

Intervention groups
This study includes 3 groups of 68 people. Embryo transfer in the first group at a depth of 0.5 to 1.5 cm from the uterine fundus, in the second group embryo transfer at a depth of 1.5 to 2.5 cm from the uterine fundus, and in the third group embryo transfer at a depth of 2.5 to 3.5 cm from the uterine fundus will be done

Main outcome variables
pregnancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220906055898N2**
Registration date: **2022-10-23, 1401/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-23, 1401/08/01**
Update count: **0**

Registration date
2022-10-23, 1401/08/01

Registrant information

Name
Ameneh Keshavarz

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3612 2227

Email address
a.keshavarzi2877@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-11, 1401/07/19

Expected recruitment end date
2022-12-20, 1401/09/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title

Comparing the depth of embryo transfer and its effect on the outcomes of frozen embryo transfer cycles: a double-blind RCT

Public title

Comparing the depth of embryo transfer and its effect on the outcomes of frozen embryo transfer cycles in infertile women applying for frozen embryo transfer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

• Candidate patients for embryo transfer between 20 and 45 years old • Patients with at least two good quality embryos for transfer • Patients with normal BMI • Patients with a healthy uterine cavity confirmed by hysterosalpingograph and hysteroscope or ultrasound.

Exclusion criteria:

• Patients with uncontrolled chronic disease • Patients with donated eggs or embryos • Patients with surrogacy • Poor responder • Patients with endometriosis problems • Non-use or irregular use of medicines • Patients with a history of more than three unsuccessful transplants (RIF) • Presence of hydrosalpinx • Patients with endometrial thickness less than 7 mm after HRT • Patients with adenomyosis • Patients whose embryos are the result of TESE or severe male factor • PGD candidate patients

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **204**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, firstly, the samples were selected based on the conditions for entering the study and based on the goal, after equalizing the demographic characteristics (age, education, and the number of previous unsuccessful transfers), among the women who were referred to Hazrat Zainab infertility treatment center for transfer. The frozen embryos that have referred themselves are selected by an easy and accessible sampling method. After that, the researcher obtains the informed consent form by referring to the selected people and introducing himself, and briefly stating the type of study and the objectives of the study; Then, the women participating in the study are randomly assigned to three intervention groups: low catheter depth, medium catheter depth, and high catheter depth. All patients are included in the study voluntarily and with the knowledge of random assignment of the intervention. It will be explained to all the participants before the start of the study that they will be randomly divided into three intervention groups of embryo transfer at a shallow depth of the uterine fundus (A), medium depth of the uterine fundus (B), and deep depth of the uterine fundus (C). will be used to randomly divide the samples using the block random allocation method. In this trial, we will have three groups of 6 blocks (including 2 people participating in drug group A, 2 people participating in drug group B, and 2 people participating in drug group C). The randomization tool is also used from random sequence generation software (software allocation Random), which in addition to simple randomization, these random sequence generation software is capable of generating random sequences by the block method. The randomization process is done by the study methodology consultant and the clinical researchers are not aware of the randomization process. For concealment, we use Concealment Allocation, which refers to the method used to perform a random sequence on the participants in the study, in such a way that the allocated group is not known before the allocation of the individual. In such a way that the assigned group is not known before assigning the individual. By using sealed opaque letter envelopes with a random sequence (Sequentially numbered, seale, opaque envelope), in this method, each of the random sequences created is recorded on a card, and the cards are placed inside the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. After being a candidate for embryo transfer; Participants, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, blinding is done in a double-blind manner, so the researcher will perform the embryo transfer at the specified depth for each patient using the codes given by the epidemiologist, and the patients are blinded to the embryo transfer depth. Groups and data will be coded, and the statistician analyzing the data will be blinded to the type of grouping and group information.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Headquarters Of Shiraz University of Medical Sciences - Zand St - Shiraz

City

Shiraz

Province

Fars

Postal code

3478671946

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.SUMS.REC.1401.418

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Biochemical pregnancy rates

Timepoint

2 weeks and 6 weeks after embryo transfer

Method of measurement

Through B-HCG test and transvaginal ultrasound

2

Description

clinical pregnancy rate

Timepoint

2 weeks and 6 weeks after embryo transfer

Method of measurement

Through B-HCG test and transvaginal ultrasound

Secondary outcomes

1

Description

pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

By transvaginl sonography

Intervention groups

1

Description

Intervention group: All patients, with or without suppuration, receive estradiol orally at a dose of 4-6 mg from the second or third day of the menstrual cycle, and after transvaginal ultrasound, the endometrium thickness is good and sufficient for embryo transfer. and then the embryos are transferred in the stage of cleavage or blastocyst.

Category

Treatment - Drugs

2

Description

Intervention group: In the first intervention group, embryo transfer will take place at a depth of 0.5 to 1.5 cm.

Category

Treatment - Drugs

3

Description

Intervention group: In the second intervention group, embryo transfer will take place at a depth of 1.5 to 2.5 cm.

Category

Treatment - Drugs

4

Description

Intervention group: In the third intervention group, embryo transfer will take place at a depth of 2.5 to 3.5 cm.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zeinabiyyeh Hospital infertility Clinic

Full name of responsible person

Ameneh Keshavarzi

Street address

Department of Obstetrics and Gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

3478671946

Phone

+98 71 3233 2365

Fax

+98 71 3233 2365

Email

s.kharati@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpour
Street address
Shiraz University of Medical Sciences, Zand St, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3230 5410
Fax
+98 71 3230 5410
Email
memarpour@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Ameneh Keshavarzi
Position
Infertility Fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3230 5410
Fax
+98 71 3230 5410
Email
s.kharati@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Ameneh Keshavarzi
Position
Infertility Fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Department of Obstetrics and Gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
3478671946
Phone
+98 71 3233 2365
Fax
+98 71 3233 2365
Email
s.kharati@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Ameneh Keshavarzi
Position
Infertility Fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran
City
Shiraz
Province
Fars

Postal code
7134814336
Phone
+98 71 3230 5410
Fax
+98 71 3230 5410
Email
s.kharati@yahoo.com

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
Not applicable
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