Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Evaluating the role of hysteroscopy in the success of in vitro fertilization (IVF)

Protocol summary

Study aim
Evaluating the role of hysteroscopy in the success of in vitro fertilization (IVF)

Design
130 infertile women with no known pathology will be randomly assigned to two groups with hysteroscopy and without hysteroscopy using a block randomization procedure.

Settings and conduct
This study will be conducted in the field of reducing disability and complications of fertility disorders and treating infertility in patients referred to the infertility clinic of Al-Zahra Hospital (S) in Tabriz. Patients will be randomly assigned to two groups with hysteroscopy and without hysteroscopy using the block randomization method. This is a open labeled (non-blinded) study.

Participants/Inclusion and exclusion criteria
Infertile women below the age of 40 have antral follicles is greater than and equal to 5 will be included in the study and if they have a history of endometrial surgery, they will be prohibited from entering the study.

Intervention groups
In both groups, ovulation stimulation is done with Letrozole, Sinal F, hMG, and cetrotide. When at least two to three 18 mm follicles are seen in the ultrasound, the oocytes are released by decapeptyl and hCG. At most, one or two cycles after hysteroscopy, from the second day of the menstrual cycle, the endometrium is ready for embryo transfer. HRT is performed with estrogen and progesterone and maximum 2 to 3 embryos of 3 days (cleavage) are transferred as Freez. Luteal phase with Progesterone ampoules and suppositories are supported until the end of the first trimester. Hysteroscopy is performed by a surgeon in the early to mid-follicular stage of the menstrual cycle, 1 to 2 months before embryo transfer.

Main outcome variables
β-hCG positive and the presence of clinical pregnancy with ultrasound

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220702055335N3**
Registration date: **2023-10-17, 1402/07/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-17, 1402/07/25**
Update count: **0**

Registration date
2023-10-17, 1402/07/25

Registrant information

Name
Parvin Hakimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3553 9161

Email address
parvin.hakimi56@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-17, 1402/07/25

Expected recruitment end date
2024-10-16, 1403/07/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluating the role of hysteroscopy in the success of in vitro fertilization (IVF)

Public title
Evaluating the role of hysteroscopy in the success of In vitro fertilization (IVF)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Primary infertility Age below 40 years Body mass index between 19 and 35 kg/m2 Couples who have not had any identifiable reason for infertility after one year of infertility investigation Hysterosalpingography based on open uterine tubes The number of antral follicles, bigger and equal 5
Exclusion criteria:
Azoospermia The History of Surgical Treatment of Endometrial History of in vitro fertilisation
Age
To **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
People will be allocated to two intervention and control groups by the method of balanced block randomization.The number of blocks is 33 and the volume inside each block is 4. The order in which the participants enter the study groups determines the order within each group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Tabriz University Of Medical Sciences
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2023-10-02, 1402/07/10
Ethics committee reference number
IR.TBZMED.REC.1402.509

Health conditions studied

1

Description of health condition studied
Female infertility
ICD-10 code
N97.9
ICD-10 code description
Female infertility, unspecified

Primary outcomes

1

Description
Chemical pregnancy rate
Timepoint
Two week after transfer
Method of measurement
BHCG≥200

Secondary outcomes

1

Description
Clinical pregnancy rate
Timepoint
Two week after transfer
Method of measurement
Observation of pregnancy sac and Fetal Heart in ultrasonography

2

Description
Rate of abortion
Timepoint
Until the 20th week of pregnancy
Method of measurement
The observation of bleeding

Intervention groups

1

Description
In the intervention group, 1 to 3 months before the start of IVF, hysteroscopy is first performed by a surgeon in

the early to mid-follicular phase of the menstrual cycle.Ovulation stimulation is done with Letrozole, Sinal F, hMG and Sterotide. When at least two to three follicles of 18 mm are seen in the ultrasound, the release of eggs is done by decapeptyl and hCG.At most one or two cycles after ovulation, from the second day of the menstrual cycle, the preparation of the endometrium for embryo transfer is done using HRT and estrogen and progesterone, and a maximum of 2 to 3 3-day-old embryos (cleavage) are transferred as Freez.The luteal phase is supported with progesterone ampoules and suppositories until the end of the first trimester

Category

Treatment - Surgery

2

Description

In the control group, two 2.5 mg letrozole tablets are given daily from the third day of menstruation until the day of hCG injection. From the third day of starting letrozole, 150 to 300 units of Sinal F ampoules are given daily until the day of hCG injection.From the second day of SinalF injection, one or two hMG is given daily until the day of hCG injection, and when the first follicle reaches 14 mm in size, one Sterotide 250 is given daily.When at least 2 to 3 18 mm follicles are detected in ultrasound, egg release is done by 10,000 units of Hcg and two ampoules of 0.1 decapeptyl, and 36 hours later, ovulation is done by vaginal ultrasound.At most one to two cycles after the second day of the menstrual cycle, 6 mg of estradiol per day is started for the patient, and when the endometrial thickness reaches at least 7 to 8 mm, 50-100 mg of intramuscular progesterone is given to the patient for 4 days. It will be given and on the fourth day of progesterone injection, transfer of 2 to 3 three-day-old embryos (cleavage) is performed for the patient.Luteal phase support is done until the end of the third month with progesterone 50mg ampoules every other day and progesterone 400 suppositories every 12 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr. Parvin Hakimi

Street address

Alzahra Hospital, South Artesh St.,Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3553 9161

Email

lahroudin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

Street address

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3335 7310

Email

research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Research,Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parvin Hakimi

Position

Assistant Professor Professor of Obstetrics Gynecology

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Tabriz University Of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5138665793

Phone
+98 41 3551 9161

Email
lahroudin@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Parvin Hakimi

Position
Assistant Professor Professor of Obstetrics Gynecology

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Tabriz University Of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5138665793

Phone
+98 35519161

Email
lahroudin@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Parvin Hakimi

Position
Assistant Professor Professor of Obstetrics Gynecology

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Tabriz University Of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5138665793

Phone
+98 35519161

Email
lahroudin@gmail.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
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