Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of uterine flushing with human chorionic gonadotropin (hCG) on biochemical and clinical pregnancy rate in the IUI cycle of couples with idiopathic infertility

Protocol summary

Study aim

Evaluation of the effect of uterine flushing with human chorionic gonadotropin (hCG) on biochemical and clinical pregnancy rate in the IUI cycle of couples with idiopathic infertility

Design

The present study will be a randomized controlled trial.The method of sampling from the population will be Simple random sampling and couples with the diagnosis of unexplained infertility will be included in the study. There are 80 couples with unexplained infertility divided to intervention and control groups(40 patients in each group) and the age of all members is between 20-38 years.

Settings and conduct

This study will be conducted in the field of infertility treatment on 80 patients referred to the infertility clinic of Alzahra Hospital in Tabriz. Patients will be randomly divided into two groups of 40 people. The control group will receive 10,000 units of hCG intramuscularly. And the intervention group, in addition to intramuscular injection, two hours before intrauterine sperm insemination (IUI), 1000 units of hCG will be diluted in half a cc of normal saline and injected directly into the uterine cavity.

Participants/Inclusion and exclusion criteria

In this study, women diagnosed with primary or secondary infertility between the ages of 20 and 38 will be included in the study if they have consent, and if they have blocked fallopian tubes or any hormonal disorder, they will be prohibited from entering the study.

Intervention groups

we inject 10000 IU intra muscular hCG in both groups. 34-36 hours later the IUI will be performed as usual. 2 hours before the IUI, In intervention group we Dilute 1000 IU hCG in 0.5 cc of normal saline and inject directly in the uterus cavity but in control group we just inject 0.5 cc of normal saline into the uterus.

Main outcome variables

Clinical pregnancy is considered as the main outcome of this study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220702055335N1**
Registration date: **2022-08-09, 1401/05/18**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-09, 1401/05/18**
Update count: **0**

Registration date

2022-08-09, 1401/05/18

Registrant information

Name

Parvin Hakimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3553 9161

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parvin.hakimi56@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2023-08-06, 1402/05/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of uterine flushing with human chorionic gonadotropin (hCG) on biochemical and clinical pregnancy rate in the IUI cycle of couples with idiopathic infertility

Public title
Evaluation of the effect of uterine flushing with human chorionic gonadotropin (hCG) on biochemical and clinical pregnancy rate in the IUI cycle of couples with idiopathic infertility
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having an informed consent to participate in the study Unexplained infertility diagnosis The health of the uterus structure Normal sperm analysis Women between 20 and 38 years old The presence of ovulation
Exclusion criteria:
unsatisfaction for the participation of study Moderate to severe endometriosis hyper prolactinemia Hyperthyroidism Hypothyroidism Ovarian Cysts Kidney and liver failure Blocked fallopian tubes Increased FSH
Age
From **20 years** old to **38 years** old
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who meet the inclusion criteria are divided into two intervention groups using simple randomization method.The randomization method used in this study is the use of a table of random numbers.Random number table is a set of numbers that is generated without a specific pattern or order and they generated randomly and they are formed in a table.In first the direction of reading the numbers was specified.To read the numbers, random numbers are read from the left side of the table, then even numbers extracted from the table are allocated to intervention group 1 and odd numbers extracted from the table are allocated to intervention group 2.
Blinding (investigator's opinion)
Double blinded
Blinding description
Before prescribing the drug to the patient, the plan is introduced and written consent is received. Study at the patient level, outcome assessor and statistical analyzer of the results will be blinded.
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
2022-06-01, 1401/03/11
Ethics committee reference number
IR.TBZMED.REC.1401.233

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
clinical pregnancy rate
Timepoint
28 days after transfer
Method of measurement
vaginal sonography

2

Description
chemical pregnancy rate
Timepoint
14 days after transfer

Method of measurement
BhCG test

Secondary outcomes

empty

Intervention groups

1

Description
Control group: At the beginning of menstruation and on the third day, an ultrasound will be performed, and from the third day of menstruation, 1 or 2 tablets of letrozole 2.5 mg will be prescribed daily for 5 days. Then, according to the age and state of ovarian reserve, We may inject Cinnal-F ampoule (Cina Gene Pharmaceuticals) 75 units subcutaneously on days 6, 8 and 10. Then on the 10th or 11th day, an ultrasound will be performed and if one or two follicles with a size larger than 18-20 mm and endometrial thickness greater than 7 mm are observed, 10,000 units of hCG will be injected intramuscularly.34-36 hours later the IUI will be performed as usual. In this group, two hours before IUI, 0.5 cc of normal saline will be injected into the uterus as a placebo.
Category
Treatment - Drugs

2

Description
intervention group: At the beginning of menstruation and on the third day, an ultrasound will be performed, and from the third day of menstruation, 1 or 2 tablets of letrozole 2.5 mg will be prescribed daily for 5 days. Then, according to the age and state of ovarian reserve, We may inject Cinnal-F ampoule (Cina Gene Pharmaceuticals) 75 units subcutaneously on days 6, 8 and 10. Then on the 10th or 11th day, an ultrasound will be performed and if one or two follicles with a size larger than 18-20 mm and endometrial thickness greater than 7 mm are observed, 10,000 units of hCG will be injected intramuscularly.34-36 hours later the IUI will be performed as usual. In this group, two hours before IUI,1000 IU hCG will be diluted in 0.5 cc of normal saline and will be injected directly in the uterus cavity.
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, iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research,Tabriz
Full name of responsible person
Dr.Parviz Shahabi
Street address
No. 2 Central Building,Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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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
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
Parvin Hakimi
Position
Associate Professor of Obstetrics Gynecology
Latest degree

Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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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