Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Dual FSH/HCG triggering on the success rate of IUI in couples diagnosed with unexplained infertilityEvaluation of the effect of Dual Follicle Stimulating Hormone(FSH)/Human Chorionic Gonadotropin hormone(HCG) triggering on the success rate ofIntrauterine insemination (IUI) in couples diagnosed with unexplained infertility.

Protocol summary

Study aim

Evaluation of the effect of Dual Follicle Stimulating Hormone(FSH)/Human Chorionic Gonadotropin hormone(HCG) triggering on the success rate ofIntrauterine insemination (IUI) in couples diagnosed with unexplained infertility.

Design

Clinical trial with control group.The number of samples will be 80 (40 patients in each group). They will be divided randomly into intervention and control groups .This study is Single blind.

Settings and conduct

This study will be conducted in Al-Zahra Hospital, Tabriz, on women whose cause of infertility is unknown.The patients will be will be divided randomly into intervention and control groups .In the control group, two ampoules of human chorionic gonadotropin (HCG) 5000 units will be injected intramuscularly. And in the intervention group, two ampoules of HCG (5000 units intramuscular) and 150 units of follicle stimulating hormone (r-FSH) will be injected subcutaneously.In both groups, 34 to 36 hours later, intrauterine sperm insemination (IUI) will be performed as usual.

Participants/Inclusion and exclusion criteria

women between the ages of 20 and 38 who are candidates for of Intrauterine insemination will be included and will be prohibited from participating in the study if they have an underlying disease .

Intervention groups

in Control group, two ampoules of human chorionic gonadotropin hormone 5000 intramuscular units will be injected intramuscularly. And In Intervention group, two ampoules of HCG 5000 intramuscular units, along with 150 units of follicle stimulating hormone, are also received subcutaneously.In both groups 34 to 36 hours later, Intrauterine insemination is performed as usual.

Main outcome variables

The success rate in clinical pregnancy is considered as the main outcome of this study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220702055335N2**
Registration date: **2022-09-06, 1401/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-06, 1401/06/15**
Update count: **0**

Registration date

2022-09-06, 1401/06/15

Registrant information

Name

Parvin Hakimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3553 9161

Email address

parvin.hakimi56@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-08-27, 1401/06/05
Expected recruitment end date
2023-08-27, 1402/06/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Dual FSH/HCG triggering on the success rate of IUI in couples diagnosed with unexplained infertilityEvaluation of the effect of Dual Follicle Stimulating Hormone(FSH)/Human Chorionic Gonadotropin hormone(HCG) triggering on the success rate ofIntrauterine insemination (IUI) in couples diagnosed with unexplained infertility.

Public title
Evaluation of the effect of Dual Follicle Stimulating Hormone(FSH)/Human Chorionic Gonadotropin hormone(HCG) triggering on the success rate ofIntrauterine insemination (IUI) in couples diagnosed with unexplained 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 pap smear test Normal sperm analysis Women between 20 and 38 years old
Exclusion criteria:
Moderate to severe endometriosis Hyper prolactinemia Hyperthyroidism Hypothyroidism Ovarian Cysts Kidney and liver failure Secondary infertility
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
Randomization and blinding will be done using the RANDOM.ORG website.Thus, for each patient, a number from 1 to 80 will be given And then, it will be obtained by the relevant site and by entering the range of random numbers.The obtained numbers will be assigned equally to two groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients will be divided randomly into two groups (A and B).The data collection form will be provided to the analyzer with the header A and B without mentioning the type of method performed on the patient. The results of the data analysis, will be provided to the analyst without mentioning the name of the method (group A and B) to examine the consequences.So, these people 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.1401.235

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

Secondary outcomes

1

Description
Chemical pregnancy rate
Timepoint
14 days after transfer
Method of measurement
BhCG test

Intervention groups

1

Description
Intervention group: after checking the state of the ovaries and ensuring the presence of at least one mature follicle larger than 18 mm (between one and five follicles) and a suitable endometrium with a thickness of at least 7 mm, two ampoules of human chorionic gonadotropin hormone(HCG) 5000 intramuscular units (manufactured by Poyesh Pharmaceutical Company Daru, Iran) along with 150 units of (follicle stimulating hormone) FSH (Two ampoules of 75 units of Cinnal F) (manufactured by Shafayab Gostar Company) are also received subcutaneously. 34 to 36 hours later, Intrauterine insemination (IUI) is performed as usual.
Category
Treatment - Drugs

2

Description
Control group: after checking the state of the ovaries and ensuring the presence of at least one mature follicle larger than 18 mm (between one and five follicles) and a suitable endometrium with a thickness of at least 7 mm, two ampoules of human chorionic gonadotropin hormone(HCG) 5000 intramuscular units (manufactured by Poyesh Pharmaceutical Company) Daru, Iran) will be injected intramuscularly. 34 to 36 hours later, Intrauterine insemination (IUI) is performed as usual.
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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5138665793
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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
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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 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
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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