

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 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

##### Email address

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  
hyperprolactinemia  
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

**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

**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

**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

**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 scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

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**Other areas of specialty/work**

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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