

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The comparison the effect of combination therapy of human chorionic gonadotropin ampoule (HCG) and Letrozole tablet with each methods alone on spermogram parameters in obese men with idiopathic infertility

Protocol summary

Study aim

The comparison the effect of combination therapy of human chorionic gonadotropin ampoule (HCG) and Letrozole tablet with each methods alone on spermogram parameters in obese men with idiopathic infertility

Design

Randomized, clinical trial with a parallel group

Settings and conduct

The aim of this study is comparing the effect of combination therapy of human chorionic gonadotropin ampoule (HCG) and Letrozole tablet with each methods alone on spermogram parameters in obese men with idiopathic infertility referred to Alzahra Infertility Clinic Center and Private Clinic in Tabriz. Patients will be randomly divided into three treatment groups. The first group received 5000 units of HCG ampoule twice in a week and the other group (group 2) will be treated with letrozole 2.5 mg daily and for the other group (group 3) will received combined treatment with 5000 units of HCG ampoule twice in a week and Letrozole tablets 2.5 mg daily. Due to the fact that a group would be injected, it was not possible to become blind.

Participants/Inclusion and exclusion criteria

En Obese men with a body mass index greater than 30, Idiopathic infertility, Age 20 to 45 years, Men with informed consent, Lack of anatomical problems

Intervention groups

Obese men with BMI greater than 30 with idiopathic infertility will randomly divided into three groups. The first group received 5000 units of HCG ampoule twice in a week and the other group (group 2) will be treated with letrozole 2.5 mg daily and for the other group (group 3) will received combined treatment with 5000 units of HCG ampoule twice in a week and Letrozole tablets 2.5 mg daily.

Main outcome variables

Spermogram test

General information

Reason for update

Acronym

HCG

IRCT registration information

IRCT registration number: **IRCT20100614004181N9**

Registration date: **2019-10-18, 1398/07/26**

Registration timing: **prospective**

Last update: **2019-10-18, 1398/07/26**

Update count: **0**

Registration date

2019-10-18, 1398/07/26

Registrant information

Name

Yadollah Ahmadi AsrBadr

Name of organization / entity

Sina Hospital

Country

Iran (Islamic Republic of)

Phone

+98 41 1329 1924

Email address

ahmadiy@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison the effect of combination therapy of human chorionic gonadotropin ampoule (HCG) and Letrozole tablet with each methods alone on spermogram parameters in obese men with idiopathic infertility

Public title

The effect of combination therapy of human chorionic gonadotropin ampoule (HCG) and Letrozole tablet on spermogram parameters in obese men with idiopathic infertility

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Obese men with a body mass index greater than 30
Idiopathic infertility Age 20 to 45 years Men with informed consent

Exclusion criteria:

Men with a history of genital surgery Men with a history of infectious disease in the genital system Men with symptoms of urinary or genital infection Men with a history of suspected contact or urethritis symptoms Men with spermatogenesis-damaging drugs such as Sulfasalazine Men with history of tobacco and alcohol or drugs consuming Men with a family history of infertility in first degree relatives Men with testicular atrophy Men with varicocele Men with changes in consistency and size of cord and vasodefran and epididymis Men with abnormalities in hormone or renal and liver tests Obese men with age less than 20-year old Obese men with age more than 45-year old Men without informed consent

Age

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

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

En The computerized block randomization (block sizes of 3 and 9) will carried out in this study. An independent clinical epidemiologist, who will not involved in the conduct of the study used a computerized block randomization program (STATA14 software) uses to produce the allocation codes. The randomization sequences will be concealed in lightproof, sealed envelopes. The research assistant opened sealed, numbered, opaque envelopes containing allocation codes. The eligible participants will be randomized to three equal groups (Letrozole tablet, HCG ampoule and

combination method) according to the randomization list after signing informed consent form.

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

Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-04-27, 1398/02/07

Ethics committee reference number

IR.TBZMED.REC.1398.097

Health conditions studied**1****Description of health condition studied**

Male idiopathic infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes**1****Description**

Sperm indices including sperm volume evaluation, sperm count, motility rate and sperm morphology

Timepoint

One day before treatment and 3 months after treatment

Method of measurement

Spermogram test

Secondary outcomes

1

Description

Serum levels of testosterone

Timepoint

One day before treatment and 3 months after treatment

Method of measurement

Evaluation of venous blood sample based on laboratory kit

2

Description

Serum levels of estradiol

Timepoint

One day before treatment and 3 months after treatment

Method of measurement

Evaluation of venous blood sample based on laboratory kit

Intervention groups

1

Description

Intervention group: Intervention group 1: HCG ampoule at a dose of 5000 units twice weekly and letrozole tablet 2.5 mg daily for 3 months

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group 1: HCG ampoule at a dose of 5000 units twice weekly for 3 months

Category

Treatment - Drugs

3

Description

Control group: Letrozole tablet 2.5 mg daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Clinic of Tabriz Alzahra Medical Center

Full name of responsible person

Yadollah Ahmadi Asrbadr

Street address

Infertility Clinic of Tabriz Alzahra Medical Center, Artesh Street, Maqsudiyeh Street, Tabriz, East Azerbaijan Province

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3553 9161

Email

info@alzahrahosp.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ata Mohammadpour

Street address

Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 4667

Email

amahmoodpoor@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Yadollah Ahmadi Asrbadr

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 4658

Email

yadollahahmadi@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Yadollah Ahmadi Asrbadr

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 4658

Email

yadollahahmadi@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Navid Khanzadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 4658

Email

navid.khanzadeh@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