Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 41 1329 1924

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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
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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
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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
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Person responsible for updating data

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Navid Khanzadeh
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Resident
Latest degree
Medical doctor
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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