Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Efficacy of low-dose human chorionic gonadotropin in late follicular phase of controlled ovarian stimulation using GnRH agonist protocol among infertile women undergoing assisted reproductive technology

Protocol summary

Study aim

The effectiveness of using a low-dose hCG supplementation in comparison with a GnRH agonist in the late follicular phase.

Design

Intervention 2: Ovarian stimulation with human menopausal gonadotropin was started from day 2 of cycle. Ovarian response was monitored by serial vaginal sonographies and evaluation of serum E2 levels. Patients received hMG until the end of ovarian stimulation.

Settings and conduct

Women younger than 38 years old who scheduled for ART were randomly divided into two groups of either hCG or hMG. In this not-blinded, phase 2 clinical trial without control group, randomization was performed using random number table.

Participants/Inclusion and exclusion criteria

All women younger than 38 years old, with regular menstrual cycles ,BMI\30 kg/m2, normal uterus and ovaries in vaginal ultrasound and basal FSH\10 IU/L were included . Women with severe endometriosis, polycystic ovary syndrome (PCOS), history of pelvic surgery, azoospermia and more than two in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) cycle failures were excluded from the study.

Intervention groups

Intervention 1: Ovarian stimulation with human menopausal gonadotropin was started from day 2 of cycle. Ovarian response was monitored by serial vaginal sonographies and evaluation of serum E2 levels. The administration of hMG was discontinued when at least six follicles >12 mm were observed and E2 levels were higher than 600 pg/ml; hMG was replaced by 200 IU per day of hCG until final follicular maturation.

Main outcome variables

Chemical pregnancy

General information

Reason for update

Updating the trial regarding actual sample size, actual recruitment start and end dates

Acronym

IRCT registration information

IRCT registration number: **IRCT201107286420N5**
Registration date: **2011-09-01, 1390/06/10**
Registration timing: **retrospective**

Last update: **2021-04-10, 1400/01/21**
Update count: **1**

Registration date

2011-09-01, 1390/06/10

Registrant information

Name

Maryam Eftekhar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

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+98 35182470856

Email address

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Recruitment status

Recruitment complete

Funding source

Yazd research and clinical center for infertility

Expected recruitment start date

2009-03-01, 1387/12/11

Expected recruitment end date

2011-01-01, 1389/10/11

Actual recruitment start date

2009-03-01, 1387/12/11

Actual recruitment end date
2010-09-30, 1389/07/08
Trial completion date
2011-05-01, 1390/02/11

Scientific title
Efficacy of low-dose human chorionic gonadotropin in late follicular phase of controlled ovarian stimulation using GnRH agonist protocol among infertile women undergoing assisted reproductive technology

Public title
Comparison of two protocols for controlled ovarian stimulation in infertile women undergoing assisted reproductive technology
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age<38 years Regular menstrual cycle (25-35 days) BMI <30 kg/m 2 Normal uterus and ovaries in vaginal ultrasound FSH<10IU/L
Exclusion criteria:
Severe endometriosis Polycystic ovarian syndrome History of pelvic surgery Azoospermia More than two IVF or ICSI cycle failures
Age
From **18 years** old to **38 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **130**
Actual sample size reached: **122**
Randomization (investigator's opinion)
Randomized
Randomization description
In this trial, infertile women who were scheduled for ART and met the inclusion criteria, informed about the research design and signed a written consent form for randomly assignment either to case or control groups. All women were randomly divided into two groups using simple, individual through random number table. All women were consecutively assigned into two groups based on randomized list.
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
Yazd Research and Clinical Center for Infertility
Street address
Bouali Ave, Safayeh
City
Yazd
Province
Yazd
Postal code
8916877391
Approval date
2010-11-10, 1389/08/19
Ethics committee reference number
2310

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Chemical pregnancy
Timepoint
2 weeks
Method of measurement
BHCG serum

Secondary outcomes

1

Description
Clinical pregnancy
Timepoint
7 weeks after embryo transfer
Method of measurement
Sonography

Intervention groups

1

Description
The control group (n=62) receive standard long protocol and gonadotropins administration continue until the day of hCG injection (10000 IU) for final follicular maturation.

Category
Treatment - Drugs

2

Description
The study group (n=60) receive GnRH long protocol. They receive 200 IU HCG instead of HMG when they have more than 6 follicles with mean diameter more than 12 mm.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd reserch and clinical center for infertility
Full name of responsible person
Dr Maryam Eftekhar
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Bouali Ave, Safaieh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology, Yazd Shahid Sadoughi Medical Sciences
Full name of responsible person
Masoud Mirzaei
Street address
Bahonar Square
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Yazd
Postal code
8916978477
Phone
+98 35 3724 0171
Email
dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research and Technology, Yazd Shahid Sadoughi 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
Research and Clinical Center for Infertility
Full name of responsible person
Dr Maryam Eftekhar
Position
Assisted Professor of Obstetrics and Gynecology
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All participant data sets are to be shared
When the data will become available and for how long
2 months after the result publication
To whom data/document is available
A journal in which the results are published
Under which criteria data/document could be used
Submission of an official application via the agent that is legally in charge
From where data/document is obtainable
A journal in which the results are published
What processes are involved for a request to access data/document
Submission of an official application via the agent that is legally in charge
Comments