

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of three drugs clomiphene, letrozole and gonadotropin on the dominant follicle and pregnancy in infertile women with polycystic ovaries: a single-blind randomized controlled trial

Protocol summary

Study aim

Comparison of the effect of three drugs clomiphene, letrozole and gonadotropin on the dominant follicle and pregnancy in infertile women with polycystic ovaries

Design

This is a single-blind randomized clinical trial with three intervention groups, phase III, in which eligible patients will be randomly assigned through the drawing of lots to the intervention groups.

Settings and conduct

This study will be performed in the Fatemeh Hospital in Hamadan city on 384 infertile women. The patients will be randomly assigned to the intervention groups through the drawing of lots. This trial will be single-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years; Primary or secondary infertility due to polycystic ovaries Exclusion criteria: Tubular problems

Intervention groups

Intervention group 1: Tablet Clomiphene (manufactured by Iran Hormone Pharmaceutical Co.) 50 mg every 12 hours for 5 days Intervention group 2: Tablet Letrozole (manufactured by Iran Hormone Pharmaceutical Co.) 2.5 mg every 12 hours for 5 days Intervention group 3: Ampulla Gonadotropin (manufactured by Empower Pharmaceutical Co.) 150 units daily for 5 days

Main outcome variables

Primary outcome: Dominant follicle formation; development of chemical pregnancy (positive pregnancy test)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N417**

Registration date: **2022-02-19, 1400/11/30**

Registration timing: **prospective**

Last update: **2022-02-19, 1400/11/30**

Update count: **0**

Registration date

2022-02-19, 1400/11/30

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2023-04-04, 1402/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of three drugs clomiphene, letrozole and gonadotropin on the dominant follicle and

pregnancy in infertile women with polycystic ovaries: a single-blind randomized controlled trial		Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave	
Public title	Comparison of the effect of three drugs clomiphene, letrozole and gonadotropin on the dominant follicle and pregnancy in infertile women with polycystic ovaries	City	Hamadan
Purpose	Treatment	Province	Hamadan
Inclusion/Exclusion criteria		Postal code	6517838695
Inclusion criteria:	Age of 18 to 35 years; Primary or secondary infertility due to polycystic ovaries	Approval date	2021-07-31, 1400/05/09
Exclusion criteria:	Tubular problems	Ethics committee reference number	IR.UMSHA.REC.1400.363
Age	From 18 years old to 35 years old	Health conditions studied	
Gender	Female	1	
Phase	3	Description of health condition studied	
Groups that have been masked	Outcome assessor	Infertile women	
Sample size	Target sample size: 384	ICD-10 code	
Randomization (investigator's opinion)	Randomized	N97	
Randomization description	Random assignment of the patients to the intervention groups through the drawing of lots. To do this, we prepare three sheets and write the drug names (clomiphene, letrozole and gonadotropin) on the sheets. Then, by referring each patient, one of the sheets will be randomly taken without replacement and the patient will be assigned to the intervention groups. This process will be repeated until we reach the sample size.	ICD-10 code description	
Blinding (investigator's opinion)	Single blinded	Female infertility	
Blinding description	The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as single-blind.	Primary outcomes	
Placebo	Not used	1	
Assignment	Parallel	Description	
Other design features		Dominant follicle formation	
Secondary Ids	empty	Timepoint	
Ethics committees		On day 14 of the menstrual cycle	
1		Method of measurement	
Ethics committee		Using ultrasonography	
Name of ethics committee	Ethics Committee of Hamadan University of Medical Sciences	2	
Street address		Description	
		Development of chemical pregnancy (positive pregnancy test)	
		Timepoint	
		One month after the intervention	
		Method of measurement	
		By measuring Beta-Hcg	
		Secondary outcomes	
		empty	
		Intervention groups	
		1	
		Description	
		Intervention group 1:Tablet Clomiphene (manufactured by Iran Hormone Pharmaceutical Co.) 50 mg every 12 hours for 5 days	
		Category	
		Treatment - Drugs	

2

Description

Intervention group 2: Tablet Letrozole (manufactured by Iran Hormone Pharmaceutical Co.) 2.5 mg every 12 hours for 5 days

Category

Treatment - Drugs

3

Description

Intervention group 3: Ampulla Gonadotropin (manufactured by Empower Pharmaceutical Co.) 150 units daily for 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Dr. Shahedeh Khansari

Street address

Fatemieh Hospital, Pasdaran Ave.

City

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Province

Hamadan

Postal code

6517838695

Phone

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Email

dr_sh_kh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Shahedeh Khansari

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Ph.D.

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