

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the Effect of Melatonin on In Vitro Fertilization (IVF) in Women with Poly Cystic Ovarian

Protocol summary

Study aim

Determination of the effect of melatonin on in vitro fertilization (IVF)

Design

Randomizes clinical trials with control groups, in parallel groups, double blind in phase 3 on 320 individuals, envelope method will be used to randomization .

Settings and conduct

Study will be conducted at the Fatemieh hospital in Hamadan on infertile women with PCOS. patients will be randomly assigned to two intervention groups (receiving melatonin + metformin and folic acid) and control group (receiving metformin and folic acid). In order to blind the study participants, metformin and melatonin capsules will be available in same shape and size(single blind).

Participants/Inclusion and exclusion criteria

inclusion criteria: Women with PCOS under 40 years old underwent IVF for the first or second time, with hyperandrogenism symptom, abnormal menstrual cycles (oligomenorrhea and amenorrhea), normal uterine cavity and normal spermogram in their husband Conditions for not entering the study: Existence of underlying disease, drug interactions, use of hormonal drugs in the last three months and defects in adequate ovarian response

Intervention groups

Intervention group: Will be treated with metformin and folic acid plus melatonin From the fifth day of menstruation until the time of Ovarian removal control group: Will be treated with metformin and folic acid without melatonin From the fifth day of menstruation until the time of Ovarian removal

Main outcome variables

Clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N11**

Registration date: **2020-06-30, 1399/04/10**

Registration timing: **prospective**

Last update: **2020-06-30, 1399/04/10**

Update count: **0**

Registration date

2020-06-30, 1399/04/10

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

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+98 81 3838 0097

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Melatonin on In Vitro Fertilization (IVF) in Women with Poly Cystic Ovarian

Public title

In Vitro Fertilization

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age <40 years No Symptoms of hyperandrogenism
Abnormal menstrual cycles Use IVF assisted reproductive techniques for the first or second time No fertility problems in the patient's spouse Natural uterine cavity according to hysterosalpingography result
Exclusion criteria:
Presence of underlying disease Drug Interactions Use of hormonal drugs in the last three months Inadequate ovarian response defects

Age
To 40 years old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: 320

Randomization (investigator's opinion)
Randomized

Randomization description
We made 16 cards and write letters MT on 8 for Metformin group and on the other 8 letters ML for Melatonin group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and open it, based on selected letter MT or ML patients will be assigned to Metformin or melatonin group and the opened envelope is left out. After completing all the envelopes, we return them to the box and repeat this process up to 20 times to reach the specified sample size.

Blinding (investigator's opinion)
Single blinded

Blinding description
Melatonin and metformin capsules will be available in the same shapes as A and B labels.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical

Science

Street address
Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838697

Approval date
2020-06-16, 1399/03/27

Ethics committee reference number
Ir.Umsaha.rec.1399.302

Health conditions studied

1

Description of health condition studied

Infertility due to polycystic ovary syndrome

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

14 day after intra uterine insemination

Method of measurement

B_HCG

Secondary outcomes

1

Description

Clinical Pregnancy

Timepoint

6 and 20 weeks after B-HCG positive

Method of measurement

sonography

Intervention groups

1

Description

Intervention group: After initial evaluations by a physician and doing uterine and ovarian ultrasounds on days 1 to 3 of the menstrual cycle will be treated with metformin plus melatonin and folic acid from the fifth day of menstruation until ovulation., At tenth day of menstruation, hCG will be prescribed and another ultrasound will be performed to check endometrium thickness , AFC and follicle size. If necessary, 75 HMG units intramuscular injected. Vaginal ultrasound is

performed until a suitable follicle size (greater than or equal to 18 mm) observed. After 36-40 hours, patients undergo IUI.

Category

Treatment - Drugs

2

Description

Control group: After initial evaluations by a physician and doing uterine and ovarian ultrasounds on days 1 to 3 of the menstrual cycle will be treated with folic acid and metformin without melatonin from the fifth day of menstruation until ovulation., At tenth day of menstruation, hCG will be prescribed and another ultrasound will be performed to check endometrium thickness , AFC and follicle size. If necessary, 75 HMG units intramuscular injected. Vaginal ultrasound is performed until a suitable follicle size (greater than or equal to 18 mm) observed. After 36-40 hours, patients undergo IUI.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh hospital

Full name of responsible person

Dr Mahnaz Yavangi

Street address

Pasdaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

dr Saeid Bashirian

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Shahid Fahmide Ave

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Web page address

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

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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