

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of melatonin on the success of invitro fertilization in women with decreased ovarian reserve.

Protocol summary

Summary

Objective: Diminished ovarian reserve (DOR) significantly decreases the success rate of Assisted Reproductive techniques (ART). In this study we study the effect of melatonin on ART outcomes of the women with DOR.

Methods: This project performed on the infertile women who were referred to the infertility center in Mother and Child Hospital, affiliated to Shiraz University of Medical Sciences for 12 months in 80 patients. Inclusion criteria were: ART for the first time, normal male factor, normal uterine cavity and presence of two of the three following criteria first; summation of bilateral AFC ≤ 6 , second; AMH ≤ 1 and third; basal FSH on the 3rd day of menstrual cycle ≥ 10 . The double blind nature of the study is explained to the couples, 40 patients are taking melatonin and the other take placebo. If the couple decline to participate, the protocol is not exactly followed or the ovaries showed poor responses to gonadotropins the cases are excluded from the study. Capsules containing 3 mg Melatonin and placebo with the same shapes. The patients or the clinicians do not know that which package contained placebo or melatonin. The subjects recommended to take one capsule every night orally before going to bed starting from the 5th day of the menstrual cycle prior to the cycle that is planned for gonadotropin stimulation. Transvaginal ultrasound Scan (TVUS) performed for all of the participants before starting the supplement and they were recommended to continue the supplement up to the time of ovum pickup. Down regulation protocol is used for all patients by subcutaneous injection of GnRH agonists, starting since the 21th day of the same cycle that melatonin was started. Ovarian response to gonadotropin stimulation was monitored by TVUS starting from the 7th day and measurement of serum estradiol (E2) levels every 3 days. Final oocyte maturation trigger by 10000 IU hCG when at least 2 follicles reached 17-18 mm diameter. Oocyte retrieval was performed 34-36 h after triggering. Luteal phase was supported by 100mg intramuscular

progesterone daily, from the day of oocyte retrieval for three days and was continued by vaginal progesterone once daily. The patients were followed and the cycle outcomes were documented. After gathering all data, the code numbers of the packages will be broken by the pharmaceuticals and data analyzed. The case and control groups are compared for the outcomes such as; duration of stimulation, dosage of gonadotropins, serum E2 level on the triggering day, number and quality of oocytes and embryos, clinical pregnancies and miscarriages .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041417264N1**

Registration date: **2014-06-08, 1393/03/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-06-08, 1393/03/18

Registrant information

Name

Sara Sadeghi

Name of organization / entity

Shiraz university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Zand street , Shiraz University of Medical Sciences

Expected recruitment start date

2014-06-20, 1393/03/30

Expected recruitment end date

2015-06-20, 1394/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of melatonin on the success of invitro fertilization in women with decreased ovarian reserve.

Public title

Effect of melatonin on fertility in women with loss of ovarian reserve

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: ART for the first time, normal male factor, normal uterine cavity and presence of two of the three following criteria first; summation of bilateral AFC ≤ 6 , second; AMH ≤ 1 and third; basal FSH on the 3rd day of menstrual cycle ≥ 10 . exclusion criteria: couple declined to participate, the protocol was not exactly followed or the ovaries showed poor responses to gonadotropins

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Shiraz university of Medical Science

Street address

Shiraz university of medical science , Zand street , Shiraz

City

Shiraz

Postal code**Approval date**

2014-02-21, 1392/12/02

Ethics committee reference number

CT-P-92-5250

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

Premature ovarian failure (POF)

ICD-10 code

E 28.3

ICD-10 code description

Decreased estrogen - Premature menopause NOS - Resistant ovary syndrome .

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

Number of ovum have received in each IVF cycle.

Timepoint

On day of ovum pick up and embryo insercion (IVF)

Method of measurement

- Measuring number of ovumes on the day of pick up in lab by pathologist under microscope (GV , MI , MII) and quality of embryo also by the same pathologist due to kind of cell division (Grade I , II , III , IV)

2**Description**

Quality of ovum have received in each IVF cycle.

Timepoint

On day of ovum pick up and embryo insercion (IVF)

Method of measurement

Measuring quality of ovumes on the day of pick up in lab by pathologist under microscope (GV , MI , MII) and quality of embryo also by the same pathologist due to kind of cell division (Grade I , II , III , IV)

3**Description**

Number of embryo have received in each IVF cycle.

Timepoint

On day of ovum pick up and embryo insercion (IVF)

Method of measurement

Measuring number of embryo on the day of pick up in lab by pathologist under microscope (GV , MI , MII) and quality of embryo also by the same pathologist due to kind of cell division (Grade I , II , III , IV)

4

Description

Quality of embryo have received in each IVF cycle.

Timepoint

On day of ovum pick up and embryo insertion (IVF)

Method of measurement

Measuring quality of embryo on the day of pick up in lab by pathologist under microscope (GV , MI , MII) and quality of embryo also by the same pathologist due to kind of cell division (Grade I , II , III , IV)

Secondary outcomes

1

Description

- Clinical pregnancy

Timepoint

- 4 - 6 weeks after embryo transferring

Method of measurement

- Serum BHCG and TVS

2

Description

Misscariage

Timepoint

4-6 week after transfer day

Method of measurement

serum BHCG and TVS

Intervention groups

1

Description

In the case group ,the patient receive melatonin by does of 3 mg/day from 5'th day of cycle till pick-up day .

Category

Treatment - Drugs

2

Description

In the control group ,the patient receive placebo capsule one every night from 5'th day of cycle till pick-up day .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mother & Child hospital

Full name of responsible person

Dr. Sara Sadeghi

Street address

Mother & Child hospital , Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Shiraz of Medical Sciences

Full name of responsible person

Dr Basire Hashemi

Street address

Shiraz medical science university , zand street , Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research, Shiraz of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz university of medical science

Full name of responsible person

Dr Sara Sadeghi

Position

Resident of GYN

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty