Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 performe 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 recommende 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) performe 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 pharmaceutics and data analyze. 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

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Name of organization / entity

Shiraz university of medical science

Country

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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 univercity 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 menopose 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 emberyo 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 emberyo 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 emberyo 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 emberyo also by the same pathologist due to kind of cell division (Grade I , II , III , IV)

3

Description
Number of emberyo have received in each IVF cycle.
Timepoint
On day of ovum pick up and emberyo insercion (IVF)
Method of measurement
Measuring number of emberyo on the day of pick up in lab by pathologist under microscope (GV , MI , MII) and quality of emberyo also by the same pathologist due to kind of cell division (Grade I , II , III , IV)

4

Description
Quality of emberyo have received in each IVF cycle.
Timepoint
On day of ovum pick up and emberyo insercion (IVF)
Method of measurement
Measuring quality of emberyo on the day of pick up in lab by pathologist under microscope (GV , MI , MII) and quality of emberyo 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 emberyo transfering
Method of measurement
- Serum BHCG and TVS

2

Description
Misscariage
Timepoint
4-6 week after trasfer day
Method of measurement
serum BHCG and TVS

Intervention groups

1

Description
]n the case group ,the paitent recieve melatonin by does of 3 mg/day from 5'th day of sycle till pick-up day .
Category
Treatment - Drugs

2

Description
]n the control group ,the paitent recieve pelacebo capsule one every night from 5'th day of sycle 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
Other areas of specialty/work
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Person responsible for scientific inquiries

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Professor of obstetrics & GYN , Fellowship of infertility

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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