Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Evaluation of the effect of sildenafil plus melatonin on fertility outcomes in infertile women with poor ovarian response undergoing assisted reproductive treatment.

Protocol summary

Study aim
Evaluation of the effect of sildenafil plus melatonin on fertility outcomes in infertile women with poor ovarian response undergoing assisted reproductive treatment.

Design
Clinical trial with a control group; with parallel groups; Randomized; Designed in 88 patients

Settings and conduct
This research will be conducted on 88 patients with poor ovarian response undergoing assisted reproductive treatment in Bandar Abbas Infertility Center and the patients will be divided into four groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Aged 18 to 45 years; Not using other vasodilator drugs such as nitric oxide and calcium channel blockers; Normal semen analysis; poor ovarian response. Exclusion: Patients with other endocrine disorders such as hyperprolactinemia, PCOS, etc.; history of ovarian surgery or ovarian endometrioma; smoker; cardiovascular disorders; unwillingness to cooperate; sildenafil sensitivity and intolerance to side effects (hot flashes, vision disorders, severe drop in blood pressure and hearing disorders)

Intervention groups
Intervention group A: sildenafil starting from the first day of the cycle until the day of egg retrieval) along with inofolic starting from the first day of the previous cycle for 40 days; Intervention group B: melatonin starting from the first day of the cycle until the day of egg retrieval along with inofolic starting from the first day of the previous cycle for 40 days; Intervention group C: melatonin , starting from the first day of the cycle until the day of egg retrieval along with sildenafil starting from the first day of the cycle until the day of retrieval Ovum with Inofolic starting from the first day of the previous cycle for 40 days; control group: Inofolic starting from the first day of the previous cycle for 40 days

Main outcome variables
Oocyte quality, oocytes number, Embryo number

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160524028038N15**
Registration date: **2023-01-14, 1401/10/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-14, 1401/10/24**
Update count: **0**

Registration date
2023-01-14, 1401/10/24

Registrant information

Name
Fatemeh Bazarganipour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 76 3366 6367

Email address
bazarganipour@hums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-06, 1401/10/16

Expected recruitment end date
2023-04-05, 1402/01/16

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of sildenafil plus melatonin on fertility outcomes in infertile women with poor ovarian response undergoing assisted reproductive treatment.

Public title
Evaluation of the effect of sildenafil and melatonin on fertility outcomes in women with poor ovarian response
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 18 to 45 years Not using other vasodilator drugs such as nitric oxide and calcium channel blockers Normal semen analysis Poor ovarian response
Exclusion criteria:
Patients with other endocrine disorders such as hyperprolactinemia, PCOS, etc. History of ovarian surgery or ovarian endometrioma Smoker Cardiovascular disorders Unwillingness to cooperate Sildenafil sensitivity and intolerance to side effects (hot flashes, vision disorders, severe drop in blood pressure and hearing disorders)
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is simple. The random allocation sequence will be determined using the "computer Random generation" computer program. The sealed envelopes encoded and non-transparent (A، B ، C ، D) for the allocation of subjects to intervention (A، B ، C) and control (D) groups will be used.
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
Ethics committee of Hormozgan University of Medical Sciences
Street address
Vice chancellor of research, Shahid Mohamadi Hospital, Bandarabbas, Hormozgan
City
Bandarabbas
Province
Hormozgan
Postal code
7916839319
Approval date
2022-12-07, 1401/09/16
Ethics committee reference number
IR.HUMS.REC.1401.305

Health conditions studied

1

Description of health condition studied
Female infertility due to poor ovarian response
ICD-10 code
N97.8
ICD-10 code description
Female infertility of other origin

Primary outcomes

1

Description
Oocyte Quality
Timepoint
2-3 hrs. after oocyte collection
Method of measurement
Microscopic Evaluation

2

Description
Number of retried oocyte
Timepoint
On day of oocyte retrieval
Method of measurement
Counting number of total oocytes with microscope

3

Description
Number of embryo
Timepoint
On the 2nd day after ICSI
Method of measurement
Observation with microscope

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A: Sildenafil (sildenafil citrate 25 mg daily; Visarsin) starting from the first day of the cycle until the day of egg retrieval) along with Inofolic (Inofolic powder 4 grams daily) starting from the first day of the previous cycle for 40 days
Category
Treatment - Drugs

2

Description
Intervention group B: Melatonin (3 mg melatonin tablets daily; Razak Pharmaceutical Company, Iran) starting from the first day of the cycle until the day of egg retrieval along with inofolic (inofolic powder 4 grams daily) starting from the first day of the previous cycle for 40 days
Category
Treatment - Drugs

3

Description
Intervention group C: Melatonin (daily 3 mg of melatonin tablets (Razak Pharmaceutical Company, Iran), starting from the first day of the cycle until the day of egg retrieval with sildenafil (daily 25 mg of sildenafil citrate; Visarsin) starting from the first day of the cycle until the day of egg retrieval with inofolic (inofolic powder 4 grams daily) starting from the first day of the previous cycle for 40 days
Category
Treatment - Drugs

4

Description
Control group: Inofolic (inofolic powder 4 grams daily) starting from the first day of the previous cycle for 40 days
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility center affiliated to Hormozgan University of Medical Sciences
Full name of responsible person
Maryam Azizi
Street address
Parastar Street, Bandarabbas, Hormozgan
City
Bandarabbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3333 0755
Email
Maryamazizikut86@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Teymoor Aghamolaei
Street address
Shahid Mohamadi Hospital, Bandarabbas, Hormozgan
City
Bandarabbas
Province
Hormozgan
Postal code
7916839319
Phone
+98 76 3333 7192
Email
taghamolaei@hums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Maryam Azizi
Position
Associate professor
Latest degree

Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Parastar Street, Bandarabbas, Hormozgan

City
Bandarabbas

Province
Hormozgan

Postal code
7919915519

Phone
+98 76 3333 0755

Email
Maryamazizikut86@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Maryam Azizi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Vice chancellor of research, Shahid Mohamadi Hospital, Bandarabbas, Hormozgan

City
Bandarabbas

Province
Hormozgan

Postal code
7916839319

Phone
076333666365

Email
maryamazizikut86@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Maryam Azizi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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Province
Hormozgan

Postal code
7916839319

Phone
076333666365

Email
maryamazizikut86@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available