Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the effect of indomethacin compared to not receiving indomethacin on fertility outcomes in infertile women with poor ovarian response under assisted reproductive treatment

Protocol summary

Study aim
Determination of the effect of indomethacin on fertility outcomes in infertile women with poor ovarian response treated with assisted reproductive methods

Design
Clinical trial with control group, with parallel groups, randomized, phase 3 on 60 patients with poor ovarian response under assisted reproductive treatment. The random assignment sequence will be determined using the program "Computer Random Generation".

Settings and conduct
This research will be conducted on 60 patients with poor ovarian response undergoing assisted reproductive treatment in Bandar-abbas infertility clinic. Patients will be divided into two intervention groups (receiving indomethacin rectal suppositories at an interval of 12 hours and then 24 hours after the initial trigger) and control (not receiving indomethacin).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 18 to 45 years; Absence of contraindications to the use of indomethacin; Normal semen analysis; poor ovarian response. Exclusion criteria: Patients with other endocrine disorders such as hyperprolactinemia; Polycystic ovary syndrome, etc.; Allergy to indomethacin or any of the ingredients of this product; History of acute attacks of asthma; urticaria or rhinitis as a result of treatment with aspirin or other non-steroidal anti-inflammatory drugs; Drug abuse; History of proctitis or recent rectal bleeding; Having nasal polyps with angioneurotic edema

Intervention groups
Indomethacin rectal suppository (100 mg) 12 hours apart and then 24 hours after the initial trigger compared to not receiving indomethacin.

Main outcome variables
Oocyte quality, oocytes number, Embryo number

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160524028038N12**
Registration date: **2022-12-02, 1401/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-02, 1401/09/11**
Update count: **0**

Registration date
2022-12-02, 1401/09/11

Registrant information

Name
Fatemeh Bazarganipour

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-26, 1401/09/05

Expected recruitment end date
2023-02-24, 1401/12/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of indomethacin compared to not receiving indomethacin on fertility outcomes in infertile women with poor ovarian response under assisted reproductive treatment

Public title
Indomethacin and fertility outcomes in infertile women with poor ovarian response

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18 to 45 years Absence of contraindications to the use of indomethacin 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 Receiving drugs affecting the metabolism of indomethacin Unwillingness to cooperate History of peptic ulcer or recurrent active gastric ulcer History of gastrointestinal lesions Allergy to indomethacin or any of the ingredients of this product History of acute attacks of asthma, urticaria, or rhinitis as a result of treatment with aspirin or other non-steroidal anti-inflammatory drugs. Drug abuse History of proctitis or recent rectal bleeding Having nasal polyps with angioneurotic edema

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: **60**

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 and B) for the allocation of subjects to intervention (A) and control (B) 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
2022-07-25, 1401/05/03

Ethics committee reference number
IR.HUMS.REC.1401.105

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
First, patients will receive 300 units of Gonal F ampoule and 150 units of human monoposal gonadotropin daily for 4 days from the second day of menstruation. Gonadotropin dose will be adjusted according to ovarian response in transvaginal ultrasound and serum estradiol concentration from day 5 of stimulation. Ultrasound will be done on the sixth day when we have at least one more follicle equal to 13. Citrotriad will start with the flexible protocol. We continue the treatment until the follicle reaches 17 mm. If the patient has more than 2 follicles of 16 mm, the trigger will be performed and 10,000 units of Human chorionic gonadotropin will be injected. Patients in the intervention group will receive indomethacin (100 mg) rectal suppositories 12 hours apart and then 24 hours after the initial trigger.
Category
Treatment - Drugs

2

Description
First, patients will receive 300 units of Gonal F recombinant FSH ampoule and 150 units of human monoposal gonadotropin daily for 4 days from the second day of menstruation. Gonadotropin dose will be adjusted according to ovarian response in transvaginal ultrasound and serum estradiol concentration from day 5 of stimulation. Ultrasound will be done on the sixth day when we have at least one more follicle equal to 13. Citrotriad will start with the flexible protocol. We continue the treatment until the follicle reaches 17 mm. If the patient has more than 2 follicles of 16 mm, the trigger will be performed and 10,000 units of HCG will be injected.
Category
Treatment - Drugs

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
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7919915519
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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
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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
Associate professor
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Vice chancellor of research, Shahid Mohamadi

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Hormozgan
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7916839319
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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