

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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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+98 76 3366 6367

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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 retrieved 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 menopausal 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 menopausal 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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+98 76 3333 0755

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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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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

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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

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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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