

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of oral NSAID (Ibuprophen) as pain relief in first trimester medical abortion in patients referring to Ayatollah Mousavi hospital

Protocol summary

Study aim

Determining the effect of oral Ibuprofen on reducing pain in medical abortions in the first trimester of pregnancy

Design

This single-blind, randomized clinical trial will be performed on 25 abortion candidates and patients will be given 400 mg of Ibuprofen lysine orally and their pain will be assessed.

Settings and conduct

This single-blind, randomized clinical trial will be performed on 25 abortion patients in a teaching hospital in Zanjan, and patients will be given 400 mg of ibuprofen lysine orally and their pain will be assessed. Patients are randomly divided into two groups by block randomization method. In this study, participants, data collectors and those who evaluate the outcome will be completely unaware of the medication prescribing protocol.

Participants/Inclusion and exclusion criteria

Women who are candidates for medical abortion in the first trimester between the ages of 18 and 40 will be enrolled the study. People with a history of gastrointestinal, kidney and coagulation problems will be excluded from the study.

Intervention groups

Patients will receive 400 mg Ibuprofen lysine orally at the same time as the first dose of misoprostol and, if necessary, this dose will be repeated every 4 hours.

Main outcome variables

Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220409054465N1**

Registration date: **2022-05-16, 1401/02/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-16, 1401/02/26**

Update count: **0**

Registration date

2022-05-16, 1401/02/26

Registrant information

Name

Lida Grrosi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 3164

Email address

lgarrosi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-07-25, 1401/05/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral NSAID (Ibuprophen) as pain relief in first trimester medical abortion in patients referring to Ayatollah Mousavi hospital

Public title

Pain relief in first trimester medical abortions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with indication for medical abortion in the first trimester

Exclusion criteria:

Gastrointestinal disorders Kidney disease Coagulopathy

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the block randomization method. The size of all blocks would be four and equal. Random allocation software is also used to generate a random sequence of blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participant, data collectors and outcome assessors, will be completely unaware of the drug prescribing protocol.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Jomhori BLV. Azadi Squ. Zanjan

City

Zanjan

Province

Zanjan

Postal code

1435689752

Approval date

2022-04-16, 1401/01/27

Ethics committee reference number

IR.ZUMS.REC.1397.269

Health conditions studied

1

Description of health condition studied

Medical Abortion

ICD-10 code

004

ICD-10 code description

Medical abortion

Primary outcomes

1

Description

Pain score

Timepoint

Every one hour until 6 hours after defecation of pregnancy products

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oral administration of 400 mg ibuprofen (single dose) from Aramis farmed factory

Category

Treatment - Drugs

2

Description

control group: single dose of oral placebo (Tablets containing starch which will be similar to ibuprofen)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology Clinic of Ayatollah Mousavi Hospital in Zanjan

Full name of responsible person

Lida Garrosi

Street address

Ayatollah Mousavi Hospital, Gavazang Road, Zanjan

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Zanjan

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Postal code
1425678922
Phone
+98 21 8806 4148
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Lgarrosi@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Samad Nadri
Street address
Zanjan University of Medical Sciences Campus, Dr.
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research@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Lida Garrosi
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics

Street address

Gynecology Clinic of Ayatollah Mousavi Hospital,
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data including the main and secondary outcomes can be shared.

When the data will become available and for how long

Access period starts from 2023

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Raw data is not available to individuals and upon request, the results of the requested statistical analysis will be available to individuals.

From where data/document is obtainable

Contact the research expert of the Infertility Clinic of Zanjan University to receive the required documents or data.

What processes are involved for a request to access data/document

To submit a request, it is enough to contact the mentioned expert and send a written and signed request to her.

Comments