Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparison of effects of acetaminophen and diclofenac received as a painkiller on the results of medical abortion with misoprostol in pregnant women

Protocol summary

Study aim

Comparison of effects of acetaminophen and diclofenac received as a painkiller on the results of medical abortion with misoprostol

Design

A clinical trial containing control group, with parallel groups, without blinding, randomized, phase 3 per 100 patients. Excel software rand function has been used for randomization.

Settings and conduct

First, consent will be received from the patients admitted to the hospital and the necessary explanations will be given to them. Then, at the time of the first usage of misoprostol, 500 mg of acetaminophen tablets for group 1 patients and 75 mg diclofenac tablets for group 2 patients will bi given. Repeated doses of analgesia are given at 6 hours and 12 hours and then at 12-hour intervals for groups 1 and 2. Repeated doses are the same as the first dose. Body temperature, pulse, blood pressure and other symptoms are monitored every hour. Women are hospitalized and examined for 4 hours after abortion and before discharge. The VAS scale is used to measure the amount of pain and results will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All women candidates for abortion in the first trimester and the second trimester of pregnancy without risk factors. exclusion criteria: All women candidates for abortion in the first trimester and the second trimester of pregnancy with risk factors.

Intervention groups

Study Members are divided into two groups: 1_acetaminophen, 2_diclofenac. In the first group, acetaminophen tablets are given to each member and diclofenac tablets are given to each member in the second group.

Main outcome variables

Comparison of the effect of acetaminophen and diclofenac on pain relief in women Which of the two drugs acetaminophen and diclofenac is more effective in controlling the patient's pain? Which of the two drugs has the least interaction with misoprostol?

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220411054506N1**
Registration date: **2022-06-15, 1401/03/25**
Registration timing: **prospective**

Last update: **2022-06-15, 1401/03/25**
Update count: **0**

Registration date

2022-06-15, 1401/03/25

Registrant information

Name

Siavash Taherikia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 935 082 0810

Email address

mail4siavash@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-08-22, 1401/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects of acetaminophen and diclofenac received as a painkiller on the results of medical abortion with misoprostol in pregnant women

Public title

Comparison of effects of acetaminophen and diclofenac received as a painkiller on the results of medical abortion with misoprostol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All the pregnant women in first trimester and second trimester (confirmed by sonography) candidates to abortion.

Exclusion criteria:

Heart disease Hypertension Asthma Uncontrol Epileptic Seizure Allergy to Prostaglandin E1

Age

From **19 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be taken by simple random sampling. Then each member of the sample will be randomly assigned to one of the two subgroups:1- acetaminophen 2- diclofenac with computer software.

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 Ilam University of Medical Sciences

Street address

Ilam University of Medical Sciences, Pajuhesh Boulevard, Banganjab

City

Ilam

Province

Ilam

Postal code

6939177143

Approval date

2022-05-22, 1401/03/01

Ethics committee reference number

IR.MEDILAM.REC.1401.009

Health conditions studied

1

Description of health condition studied

Medical Abortion

ICD-10 code

O02.1

ICD-10 code description

Missed abortion

Primary outcomes

1

Description

The effect of acetaminophen and diclofenac on the outcome and success of misoprostol abortion

Timepoint

The beginning and end of the medical abortion process

Method of measurement

View the abortion result at the end of the process

Secondary outcomes

1

Description

Comparison of the effects of acetaminophen and diclofenac on pain relief

Timepoint

At the beginning of the abortion process and four hours apart until the end of the abortion

Method of measurement

According to the numerical scale of pain rating

Intervention groups

1

Description

Acetaminophen group: 500 mg acetaminophen tablets are prescribed for patients in this group. Repeated doses of analgesia are given at 6 hours and 12 hours and then at 12-hour intervals. Repeated doses are the same as the first dose.

Category
Treatment - Drugs

2

Description
Diclofenac group: Diclofenac 75 mg tablets are prescribed for patients in this group. Repeated doses of analgesia are given at 6 hours and 12 hours and then at 12-hour intervals. Repeated doses are the same as the first dose.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ilam Taleghani Hospital
Full name of responsible person
Dr Elham Pournajaf
Street address
NO 1, Khabarnegar Ave, Shahid Beheshti Boulevard
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6939177143
Phone
+98 44 2227 1430
Email
ilamtaleghanihospital@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Dr Abbas Maleki
Street address
Deputy of Research and Technology, Ilam University of Medical Sciences, Pajuhesh Boulevard
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6939177143
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info@medilam.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam University of Medical Sciences
Proportion provided by this source
5
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
Ilam University of Medical Sciences
Full name of responsible person
Siavash Taherikia
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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Contact

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A Level or less

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available