

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison the effect of rectal and oral misoprostol in First Trimester of Pregnancy Induced Abortion

Protocol summary

Summary

This clinical trial study is designed to aid in selection of most effective way of prescribe of misoprostol that had least complications. This double blind study will do on 140 pregnant women 18-35 years with singleton pregnancy IUFD below 14 w and BMI 19.8-26 kgr/m² that divided accidentally in two 70 cases groups. first group received rectal misoprostol and second group oral misoprostol in similar doses 600-300-300 microgram/6 hours and effects of drug in inducing of incomplete abortion, complete abortion .ripening of uterine cervix and side effect of drug such as nausea ,vomiting.fever and so time of effect of drug will compared in two ways.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042533635N1**

Registration date: **2017-06-21, 1396/03/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-21, 1396/03/31

Registrant information

Name

nahid sakhavar

Name of organization / entity

zahedan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 33419522

Email address

sakhavarn@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of research and technology of Zahedan university of medical sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of rectal and oral misoprostol in First Trimester of Pregnancy Induced Abortion

Public title

Comparison the effect of rectal and oral misoprostol in First Trimester of Pregnancy Induced Abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Including factors: singleton pregnancy ,gravid 2 -4, without cervical dilatation and bleeding or tissue passing, report of IUFD in two sonographys, gestational age below 14 w, BMI Between 19.8-26 kg/m² Excluding factors: background diseases related with study such as overt DM, chronic Hypertension, SLE, fever or chorioamnionitis signs, using unusual drugs in pregnant women, addiction, ...

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: 140

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

clinical trial in hospital for selection the better treatment

Secondary Ids

1

Registry name

No

Secondary trial Id

No

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

zahedan university of medical sciences

Street address

Dr hesabi square,khaligfars Blvd,administrative complex of zahedan medical sciences university pardis, Zahedan,Iran

City

zahedan

Postal code

98167-43463

Approval date

2017-03-05, 1395/12/15

Ethics committee reference number

IR.ZAUMS.REC.1395.100

Health conditions studied

1

Description of health condition studied

induced abortion

ICD-10 code

094-099

ICD-10 code description

other obstetric conditions-not elsewhere classified

Primary outcomes

1

Description

complete abortion

Timepoint

during hospitalization

Method of measurement

uterine sonogeraphy

2

Description

incomplete abortion

Timepoint

during hospitalization

Method of measurement

uterine sonogeraphy

3

Description

cervical ripening

Timepoint

during hospitalization and in time of curettage

Method of measurement

passing the number 8 bugie

4

Description

nausia

Timepoint

during hospitalization

Method of measurement

observation and patient expression

5

Description

vomitting

Timepoint

during hospitalization

Method of measurement

observation

6

Description

fever

Timepoint

during hospitalization

Method of measurement

body temperature > 38 c

7

Description

time of drug effect

Timepoint

repetitive visit and patient expression

Method of measurement

observation and examination

Secondary outcomes

empty

Intervention groups

1

Description

Misoprostol tab 200 microgram with primary dose of 600 and two dose of 300 per 6 hours in first group by rectally

Category

Treatment - Drugs

2

Description

Misoprostol tab 200 microgram with primary dose of 600 and two dose of 300 per 6 hours in second group by orally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

ali ebne abitaleb hospital zahedan

Full name of responsible person

nahid sakhavar

Street address

khalijfars highway,salamat blvd,speciality hospital of ali ebne abitaleb

City

zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

deputy of research and technology of zahedan university of medical sciences

Full name of responsible person

hoshang rafighdoost

Street address

Iran,Zahedan,Dr hesabi square,pardis administrative complex of zahedan medical university

City

zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

deputy of research and technology of zahedan university

of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

zahedan university of medical sciences

Full name of responsible person

mina khaje

Position

medical student

Other areas of specialty/work

Street address

zahedan university of medical sciences

City

zahedan

Postal code

9816743111

Phone

+98 54 3329 5570

Fax

+98 54 3329 5570

Email

nsakhavar@yahoo.co.uk

Web page address

/http://alihos.zaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

associated professor

Full name of responsible person

nahid sakhavar

Position

associate professor of obstetric and gynecology

Other areas of specialty/work

Street address

Iran,Zahedan,Ali ebne abitaleb hospital.obstetric and gynecology department

City

zahedan

Postal code

9816743111

Phone

+98 54 3329 5570

Fax

+98 54 3329 5570

Email

sakhavarn@zaums.ac.ir

Web page address

/http://alihos.zaums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

zahedan university of medical sciences

Full name of responsible person

nahid sakhavar

Position

associate professor of obstetric and gynecology

Other areas of specialty/work**Street address**

Iran,Zahedan,Ali ebne abitaleb hospital.obstetric and gynecology department

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Fax

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Email

sakhavarn@zaums.ac.ir

Web page address

/http://alihos.zaums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty