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 yearrs 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
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Person responsible for scientific inquiries

Contact
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associated professor
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associate professor of obstetric and gynecology
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Person responsible for updating data

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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