Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Clinical trial of the efficacy of misoprostol with folley catheter (traction) and rising induction in second trimester termination in Fatemieh Hospital, Hamedan

Protocol summary

Summary

In this randomized clinical trial we will recruit the pregnant women in second trimester who will be admitted for termination of pregnancy due to medical indications. The patients will be randomly assigned in two groups of traction and rising induction & misoprostol. The main study goal is to compare these two groups from the aspect of time of delivery, need to curettage and side-effects in each groups. Before starting the research, we will talk to women about each methods and their possible side-effects for signing the informed consent. The outcomes will be compared in study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103146066N1**
Registration date: **2011-10-13, 1390/07/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-10-13, 1390/07/21

Registrant information

Name

Maryam Habibi Kiasaraee

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 7082

Email address

m.habibikia@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2011-02-25, 1389/12/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the efficacy of misoprostol with folley catheter (traction) and rising induction in second trimester termination in Fatemieh Hospital, Hamedan

Public title

The effect of misoprostol with folley catheter (traction) & Rising induction in second trimester termination

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All pregnant women admitted for trmination of pregnancy in second trimester with medical indications and don`t have any contraindication for study intervention; such as heart failure, severe anemia, using high dose corticosteroids and history of adrenal failure or allergic reaction Exclusion criteria: All women are not in mid-trimester and they do not accept to participate in the study

Age

From **14 years** old to **42 years** old

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Hamedan University of Medical Sciences
Street address
Hamedan University of Medical Sciences, Fahmideh boulvar, Hamedan
City
Hamedan
Postal code
Approval date
2009-07-21, 1388/04/30
Ethics committee reference number
58470/7/70/16/پ

Health conditions studied

1

Description of health condition studied
Abortion
ICD-10 code
O04
ICD-10 code description
Medical abortion

Primary outcomes

1

Description
Time from beginig the induction to delivery
Timepoint
Time of beginig the induction till 48 hours
Method of measurement
Hour

2

Description
Need for curettage
Timepoint
30 minute till one hour after delivery
Method of measurement
Standard teatment protocol

Secondary outcomes

1

Description
The days of admission in hospital
Timepoint
Study period
Method of measurement
Medical documents reports

2

Description
Possible side-effect
Timepoint
Study period
Method of measurement
Medical documents reports

Intervention groups

1

Description
Intervention group: A 16-foley catheter will be put in the cervix, until upper end of it in the internal os; then its collecting bag will be filled with saline and then we will pull the catheter down. In that time we will administer 2gr ampicillin intravenously for prophylaxy three times a day. Then we will do rising induction simultaneously. 50Uoxytocin in 500cc ringer or ringer lactate solution will be administered in 3 hours then dieresis will be induced for an hour with D5W %(500cc). Maximum dose of oxytocin is 300u.
Category
Treatment - Other

2

Description
In control group: misoprostol (200microgram) vaginal suppository will be administered until 1400 microgram per day for achieving treatment effect or presence of side-effects
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh obstetrics & gynecology center, Hamedan

Full name of responsible person
Dr.Shohreh Alimohammadi

Street address
Fatemieh obstetrics & gynecology center

City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Hamedan University of Medical Sciences

Full name of responsible person
Dr. Ali Ghaleiha

Street address
Hamedan University of Medical Sciences, Fahmideh boulvar, Hamedan

City
Hamedan

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Hamedan 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
Hamedan University od Medical Sciences

Full name of responsible person
Dr. Shohreh Alimohammadi

Position
Perinatalogist

Other areas of specialty/work

Street address
Hamedan University od Medical Sciences

City
Hamedan

Postal code

Phone
+98 81 1827 7013

Fax

Email
m.habibikia@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Fatemieh hospital

Full name of responsible person
Dr. Shohreh Alimohammadi

Position
Perinatalogist

Other areas of specialty/work

Street address
Hamedan University od Medical Sciences

City
Hamedan

Postal code

Phone
+98 81 1827 7013

Fax

Email
m.habibikia@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University od Medical Sciences

Full name of responsible person
Maryam Habibi Kiasaraee

Position
Obstetrics & gynecology assistance

Other areas of specialty/work

Street address
Fatemieh obstet & gynecologic center

City
Hamedan

Postal code

Phone
+98 988118277013

Fax

Email
m.habibikia@gmail.com; m.habibikia@umsha.ac.ir

Web page address

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