

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

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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.

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

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

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Phone

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Email address

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 boultvar, 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

Perinatologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Obstetrics & gynecology assistance

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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