

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of Extra-Amniotic Normal Saline Infusion plus Hydrocortisone versus Prostaglandin E2 Suppository for Pregnancy Termination

Protocol summary

Summary

The aim of this study was to compare of Extra-amniotic Normal Saline plus Hydrocortisone infusion (EASHI) versus prostaglandin E2 suppository for second-trimester pregnancy termination. A randomized clinical trial study was performed on 50 pregnant women with gestational age of 14-28 weeks and Bishop Score ≤ 2 who required pregnancy termination for fetal indications and randomly assigned to the two groups of 25. In EASHI group (25 patients), a coworker inserted a No. 14 Foley catheter through the cervical canal and balloon was filled with 20 ml water and fixed. Then 360 ml sterile Normal Saline with 100 mg. Hydrocortisone was infused at a rate of 30 ml per hour into the extra amniotic space and continued up to 12 hours maximum. The Prostaglandin group (25 patients) was received two doses of prostaglandin E2 intra vaginal suppository (Dinoprostone) 3mg every 4 hour. In both groups, 6 hours after the last dose of prostaglandin and removal of Foley catheter, induction with high dose Oxytocin (according to Alabama University Protocol) was initiated up to 24 hours maximum. Mean interval time between initiation of induction and delivery, success rate of pregnancy termination, need for curettage, complications such as fever, nausea, vomiting, diarrhea and increase of blood pressure were compared in two groups.

General information

Acronym

EASI

IRCT registration information

IRCT registration number: **IRCT201109107520N1**

Registration date: **2011-12-29, 1390/10/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-29, 1390/10/08

Registrant information

Name

Farahnaz Keshavarzi

Name of organization / entity

Kermanshah University of Medical Sciences (KUMS)

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences (KUMS)

Expected recruitment start date

2004-04-20, 1383/02/01

Expected recruitment end date

2005-01-20, 1383/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Extra-Amniotic Normal Saline Infusion plus Hydrocortisone versus Prostaglandin E2 Suppository for Pregnancy Termination

Public title

Extra-Amniotic Normal Saline Infusion plus Hydrocortisone versus Prostaglandin E2 Suppository for Pregnancy Termination

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :Multiparous Jreater than or equal to 4; Bishop Score less than or equal to 2; Gestational age 14-28 weeks; Amniotic sac intact; Fetal indication of Pregnancy Termination. Exclusion criteria : Placenta Previa; Uterus Anomalies; Rupture of Membrane; History of Hypertension; Fever; Cardiac Disease; Previous Scar on the Uterus; Drug Sensitivity (Prostaglandin E2 and Hydrocortisone); contraction of uterus.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Kermanshah University of Medical Sciences

Street address

Vice Chancellor for research, Kermanshah University of Medical Sciences (KUMS), Building No. 2, Shahid Beheshti Blvd

City

Kermanshah

Postal code

Approval date

2011-09-27, 1390/07/05

Ethics committee reference number

7/420/30233/P

Health conditions studied

1

Description of health condition studied

Induction of labor, termination of pregnancy

ICD-10 code

O04

ICD-10 code description

Medical abortion: Incl: termination of pregnancy: legal

Primary outcomes

1

Description

Mean time from initiation of induction till expulsion of conception.

Timepoint

Hour

Method of measurement

Excretion products of pregnancy

Secondary outcomes

1

Description

The need to curettage

Timepoint

24 hours after fetus expulsion

Method of measurement

Residual of conception based on ultrasonography

2

Description

Uterus hyperten

Timepoint

Hour

Method of measurement

The Uterine contractions of more than two minutes

3

Description

Placenta retention

Timepoint

Every 20 minutes

Method of measurement

Retention of placenta up to half an hour after expulsion of fetus

4

Description

Success rate of pregnancy termination

Timepoint

hour

Method of measurement

Expulsion of pregnancy conception

5

Description

Diarrhea
Timepoint
Every 4 hours
Method of measurement
The passage of three or more loose or watery stools a day

6

Description
Fever
Timepoint
Every 4 hours
Method of measurement
Temperature above 38 ° C sublingual

7

Description
Hypertension
Timepoint
Every 4 hours
Method of measurement
Blood pressure greater than or equal to 140/90 mm Hg

8

Description
Hypotension
Timepoint
Every 4 hours
Method of measurement
Blood pressure less than 90/70 mm Hg

9

Description
Tachy systole
Timepoint
Hour
Method of measurement
More than 6 uterine contractions in ten minutes

10

Description
Nausea, vomiting
Timepoint
Every 4 hours
Method of measurement
Based on patient complaints and symptoms of disease by observing investigator

Intervention groups

1

Description
Prostaglandin group (25 patients) was received two doses of prostaglandin E2 intra vaginal suppository (Dinoprostone) 3mg every 4 hour. In both groups, 6 hours after the last dose of prostaglandin and removal of Foley catheter, induction with high dose Oxytocin

(according to Alabama University Protocol) was initiated up to 24 hours maximum.

Category
Treatment - Drugs

2

Description
In EASHI group (25 patients), under sterile conditions, a coworker inserted a No. 14 Foley catheter through the cervical canal and balloon was filled with 20 ml water and fixed. Then 360 ml sterile Normal Saline with 100 mg. Hydrocortisone was infused at a rate of 30 ml per hours into the extra amniotic space. The Foley catheter was checked every hour for spontaneous expulsion. If it was tolerated by patients, the infusion continued up to 12 hours maximum. In both groups, 6 hours after the last dose of prostaglandin and removal of Foley catheter, induction with high dose Oxytocin (according to Alabama University Protocol) was initiated up to 24 hours maximum.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical Center of Motazedi
Full name of responsible person
Dr. Farahnaz Keshavarzi
Street address
Imam Reza Hospital, Parastar Blvd., Sorkheh Lyzheh, Kermanshah University of Medical Sciences (KUMS)
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research, Kermanshah University of Medical Sciences (KUMS)
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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, Kermanshah University of

Medical Sciences (KUMS)
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

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Person responsible for general inquiries

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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