Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

Country

Iran (Islamic Republic of)

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+98 83 3724 2893

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fnkeshavarzi@kums.ac.ir

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 :Multiparus ¸reater 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 expultion of conception.
Timepoint
Hour
Method of measurement
Excretion products of pregnancy

Secondary outcomes

1

Description
The need to curettage
Timepoint
24 hours after fetus expultion
Method of measurement
Residual of conception based on ultrasonography

2

Description
Uterus hyperton
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
Expultion 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)

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr. Farid Najafi

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

City

Kermanshah

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

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences (KUMS)

Full name of responsible person

Dr. Farahnaz Keshavarzi

Position

Assistant Professor and Faculty Member of Kermanshah University of Medical Sciences

Other areas of specialty/work

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Contact

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Kermanshah University of Medical Sciences (KUMS)

Full name of responsible person

Sara Daee Chin

Position

Bachelor of Midwifery - Delivery Research Centre experts

Other areas of specialty/work

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mrc.kums@yahoo.com

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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