

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\leq 2$  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)

###### Phone

+98 83 3724 2893

###### Email address

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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 :Multiparus 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 Lyzkeh, 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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**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

### Contact

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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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*