

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Comparison extra amniotic saline infusion and vaginal isoniazide for cervical ripening before induction and labour duration in term and post term pregnancy

#### Protocol summary

##### Summary

The aim of this study is to assess the efficacy of intravaginal isoniazide compared with extra amniotic saline infusion for cervical ripening at term and post term. In this randomized single-blind controlled trial 150 pregnant women who will schedule for labor induction, with Bishop Score <5 is recruited. The efficacy of medications is evaluated by preterm primary and secondary outcome variable for cervical ripening and induction and delivery. Inclusion criteria are vertex presentation and single tone pregnancy. Exclusion criteria are intra uterine growth restricting, preeclampsia and rupture of membrane.

#### General information

##### Acronym

EASI: Extra amniotic saline infusion.

##### IRCT registration information

IRCT registration number: **IRCT2015040721506N2**

Registration date: **2015-04-28, 1394/02/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-04-28, 1394/02/08

##### Registrant information

###### Name

Ladan Haghighi

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 64345

##### Email address

haghighi.l@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2015-01-02, 1393/10/12

##### Expected recruitment end date

2015-07-20, 1394/04/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison extra amniotic saline infusion and vaginal isoniazide for cervical ripening before induction and labour duration in term and post term pregnancy

##### Public title

Comparison extra amniotic saline infusion and vaginal isoniazide for cervical ripening before induction and labour duration in term and post term pregnancy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1- single tone pregnancy 2- bishop score<5. Exclusion criteria: 1-macrosomia EFW> 5 Kg. 2- not reassuring NST. 3- PROM 4-AFI<5 Cm. 5- history of kidney and liver diseases. 6-history of Cesarean section. 7- low lying placenta. 8- any contraindication of isoniazide such as vomiting, nausea, visual defect, vertigo. 9- no cephalic presentation. 10- unexplained vaginal bleeding. 11- labor phase. 12- organic disease. 12- grand multiparity

**Age**

From **17 years** old to **43 years** old

**Gender**

Female

**Phase**

1

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**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**

Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, near Milad tower,  
Hemmat highway

**City**

Tehran

**Postal code****Approval date**

2015-02-14, 1393/11/25

**Ethics committee reference number**

93/105/5534/3

**Health conditions studied****1****Description of health condition studied**

Pregnancy

**ICD-10 code**

Z34

**ICD-10 code description**

Normal pregnancy

**Primary outcomes****1****Description**

Bishop score

**Timepoint**

Before intervention and before induction

**Method of measurement**

Clinical examination

**Secondary outcomes****1****Description**

Interval intervention until active phase

**Timepoint**

Start of intervention till delivery

**Method of measurement**

Minutes

**2****Description**

Interval between intervention till labour

**Timepoint**

Start of intervention till delivery

**Method of measurement**

Minutes

**3****Description**

time interval between intervention till induction of labour

**Timepoint**

start of intervention

**Method of measurement**

minute

**4****Description**

Complication vomiting and nausea and icter and vertigo

**Timepoint**

Start of intervention till delivery

**Method of measurement**

Examination and question

**Intervention groups****1****Description**

In another group foley catheter is applied in cervix extra amniotic which bubble filled with 40 mili litre strilewater

**Category**

Other

**2****Description**

In one group vaginal isoniyazide is applied 900 mg tablets every 4 hours for 3 doses.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahid Akbar Abadi hospital

**Full name of responsible person**

Dr. Samira Saadatjoo

**Street address**

Shahid Akbar Abadi hospital, Molavi street

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mrs. Irani

**Street address**

Fifth floor, Research departman, Iran University of Medical Sciences, Hemmat highway

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Samira Saadatjoo

**Position**

MD, obsetrics resident

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

#### Contact

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Ladan Haghighi

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Professor

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## Person responsible for updating data

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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*