

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)

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Email address

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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 Caesarian 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

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

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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

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

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Full name of responsible person

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Web page address

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