

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of early amniotomy and put amniotic sac in its own on the risk of dystocia in nulliparous women attending to Khorram Abad Assail hospital in 1392.

Protocol summary

Summary

Recently, early amniotomy has been supported to prevention of dystocia in spontaneous labour, but there is disagreement about amniotomy performed routinely or not for expedited delivery. In our study we find that routine early amniotomy for Nulliparous women versus put amniotic sac in its own reduce risk of dystosia or not? in addition we study other related items such as duration of labour, cord prolapse and placental abruption. in this clinical trial study, sampling will perform convenience. sampling will consisted of 300 people. the study population is all of the nulliparous women that referred to hospital with spontaneous onset of labour that have inclusion criteria. they are divided randomly into 2 groups: control and case. in case group early amniotomy at 4 CM will perform and in control group put amniotic sac in its own and we compare dystosia in two groups. basic inclusion criteria is: nulliparity, spontaneous onset of labour, exclusion criteria is each type of baseline disease in mother and fetus.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080114123N1**

Registration date: **2013-09-15, 1392/06/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-09-15, 1392/06/24

Registrant information

Name

Samira Moliini Nasab

Name of organization / entity

Lorestan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences

Expected recruitment start date

2013-09-19, 1392/06/28

Expected recruitment end date

2013-12-06, 1392/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of early amniotomy and put amniotic sac in its own on the risk of dystocia in nulliparous women attending to Khorram Abad Assail hospital in 1392.

Public title

Early amniotomy in nulliparous women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: nulliparity; single fetus; term gestational age(37 W+0day-42Weeks); Blood pressur <140/90; spontaneus onset of labour; cephalic presentation; intact amniotic memberans; normal fetal heart rate Exclusion criteria: 40<age>18; intra uterine

growth retardation; pre eclampsia; underline disease for example DM; servical dilatation $\geq$ 4 cm.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

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

Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Siences, University
Complex Kamalvand, Khorramabad, Lorestan.

City

Khorramabad

Postal code

Approval date

2013-05-22, 1392/03/01

Ethics committee reference number

200/85956

Health conditions studied

1

Description of health condition studied

dystosia

ICD-10 code

066.4

ICD-10 code description

Failed trial of labour, unspecified

Primary outcomes

1

Description

dystosia

Timepoint

delivery time

Method of measurement

Determined by obstetricians or midwives

Secondary outcomes

1

Description

time of delivery

Timepoint

during delivery

Method of measurement

Determined by obstetricians or midwives

2

Description

type of delivery

Timepoint

eduring delivery

Method of measurement

Determined by obstetricians or midwives

3

Description

cord prolapse

Timepoint

during delivery

Method of measurement

Determined by obstetricians or midwives

4

Description

placental abruption

Timepoint

during delivery

Method of measurement

Determined by obstetricians or midwives

Intervention groups

1

Description

in control group: put amniotic sac in its own

Category

Prevention

2

Description

in Intervention group underwent amniotomy will be at 4
cm dilation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

khorrām Abad Assail hospital

Full name of responsible person

Masome Ghafar Zade

Street address

Assaly khorrām abad charity hospital, Pelestin street,
Khorram abad, Lorestan.

City

Khorram abad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Mohamad Hasan Kaedi

Street address

Lorestan Univercity of Medical Siences,Academic
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Tehran, Khorram abad,Lorestan.

City

Khorram abad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Lorestan 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

Lorestan University of Medical Sciences

Full name of responsible person

Masome Ghafar Zade

Position

Gynecologist

Other areas of specialty/work

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Position

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Other areas of specialty/work

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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