

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 Moieni Nasab

##### Name of organization / entity

Lorestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1337 0277

##### Email address

zibaei.m@lums.ac.ir

##### 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; spontaneous 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 Sciences, 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

during 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**

khorrAm Abad Assail hospital

**Full name of responsible person**

Masome Ghafar Zade

**Street address**

Assaly khorrAm 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  
Complex Kamalvand, kilometer 5 khorrAm abad road  
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**

**Street address**

Lorestan univercity of Medical Siences,Academic  
Complex Kamalvand, kilometer 5 Khorram abad road

Tehran, Khorram abad, Lorestan.

**City**

Khorramabad

**Postal code**

**Phone**

+98 66 1221 5744

**Fax**

**Email**

masome hgafar zade@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Khorram abad University of Medical Sciences

**Full name of responsible person**

Masome Ghafar Zade

**Position**

Gynecologist

**Other areas of specialty/work**

**Street address**

Lorestan Univercity of Medical Siences,Academic  
Complex Kamalvand, kilometer 5 Khorram abad road  
Tehran, Khorram abad, Lorestan.

**City**

Khorram abad

**Postal code**

**Phone**

+98 66 1221 5744

**Fax**

**Email**

masomeghafarzade@yahoo.com

**Web page address**

## Person responsible for updating data

#### 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**

**Street address**

Lorestan Univercity of Medical Siences,Academic  
Complex Kamalvand, kilometer 5 Khorram abad road  
Tehran, Khorram abad, Lorestan.

**City**

Khorram abad

**Postal code**

**Phone**

+98 66 1221 5744

**Fax**

**Email**

masomeghafarzade@yahoo.com

**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*