

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the Effectiveness of Early and late Amniotomy in Delivery Outcomes in primigravida women

Protocol summary

Study aim

1. Determine and compare the effect of early and late amniotomy on the outcomes of labor

Design

In this clinical trial study with control group, 70 non-complicated pregnant women with term pregnancy and beginning of spontaneous labor are randomly divided into two groups: Intervention group 1 or early amniotomy (<4 cm) and Intervention group 2 or late amniotomy (≤4 cm). The duration of labor and Apgar score were compared in two groups.

Settings and conduct

Pregnant women who referred to the Imam Ali Hospital(Amol), and had a tendency to participate in research and normal delivery conditions, were randomly divided into two groups. Written consent was received from them after the explanation of the terms of the work.

Participants/Inclusion and exclusion criteria

Major entry conditions: Primigravida pregnant women; and Major exit conditions: Multiple pregnancy, Preterm labor, Previous cesarean section.

Intervention groups

Intervention group 1 or early amniotomy group
Intervention group 2 or late amniotomy group

Main outcome variables

The length of the first stage of labor, the length of the second stage of labor, and the length of the third stage of labor, first minute Apgar, fifth minute Apgar.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120630010147N3**

Registration date: **2018-11-11, 1397/08/20**

Registration timing: **retrospective**

Last update: **2018-11-11, 1397/08/20**

Update count: **0**

Registration date

2018-11-11, 1397/08/20

Registrant information

Name

omolbanin zare

Name of organization / entity

Islamic Azad University of Babol Branch

Country

Iran (Islamic Republic of)

Phone

+98 12 1323 9525

Email address

zare@baboliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University of babol branch

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-09-21, 1395/06/31

Actual recruitment start date

2016-06-04, 1395/03/15

Actual recruitment end date

2016-11-05, 1395/08/15

Trial completion date

2017-04-09, 1396/01/20

Scientific title

Comparison of the Effectiveness of Early and late Amniotomy in Delivery Outcomes in primigravida women

Public title

Early and late Amniotomy

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
 primigravida pregnant women who have normal delivery conditions They are 20 to 35 years old Single and live birth fetus (37-40 weeks) is with a cephalic presentation Water bag is healthy

Exclusion criteria:
 Multiple pregnancy Preterm labor Previous cesarean section Severe preeclampsia Maternal diabetes mellitus Fetal distress

Age
 From **20 years** old to **35 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **70**
 Actual sample size reached: **70**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In the first stage, pregnant women were randomly assigned to one of two groups using two envelopes containing early or late amniotomy procedure, the first person in the late amniotomy group and the next in the group of early amniotomy, and thus continued.

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
 Ethics Committee of Islamic Azad University, Babylon Branch

Street address
 Islamic Azad University of Babol Branch, 3 km Babol Road to Qa'em city

City
 Babol

Province
 Mazandaran

Postal code
 47471-37381

Approval date
 2018-09-02, 1397/06/11

Ethics committee reference number
 IR.IAU.BABOL.REC.1397.002

Health conditions studied

1

Description of health condition studied

Amniotomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The length of the first stage of labor

Timepoint

The end of the first stage

Method of measurement

A clock

2

Description

The length of the second stage of labor

Timepoint

The end of the second stage

Method of measurement

A clock

3

Description

The length of the third stage of labor

Timepoint

The end of the third stage

Method of measurement

A clock

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group or early amniotomy, which was done the rupture of the membranes in the dilatation less than 4 cm, and Amniotomy was performed with a device called the amniotomy hook of Qavami's manufactured products in Irn.

Category

N/A

2

Description

Control group: The control group or the late amniotomy, which was done the rupture of the membranes in the dilatation equal to or greater than 4 cm, based on

routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Mahbobeh Baghipour

Street address

Imam Ali Hospital, Noor Road

City

Amol

Province

Mazandaran

Postal code

4149746171

Phone

+98 11 4426 4662

Email

baghipour425@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University of Babol Branch

Full name of responsible person

Reza changizi

Street address

Islamic Azad University of Babol Branch, 3 km from
Babol Road to Qa'em city

City

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Province

Mazandaran

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Phone

+98 11 3241 5078

Email

changizi@baboliau.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University of Babol Branch

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University of Babol Branch

Full name of responsible person

Ommolbanin Zare

Position

Academic staff

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University of Babol Branch

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Academic staff

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Person responsible for updating data

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Email

mahyazare@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only part of the main outcome is shared.

When the data will become available and for how long

The start of the access period will be 6 months after the publication of the results.

To whom data/document is available

Data will be available to researchers working in academic institutions.

Under which criteria data/document could be used

To advance science

From where data/document is obtainable

mahyazare@yahoo.com

What processes are involved for a request to access data/document

If properly claimed in less than a week

Comments