

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of labor outcome in induction with and without early amniotomy in nulliparous pregnant women with gestational age of 41 weeks and more

Protocol summary

Study aim

Determination of early amniotomy's effect in nulliparous pregnant women with gestational age of 41 weeks and more

Design

160 Patients with gravid one post term pregnant conditions, were Classified in two groups : control and early amniotomy; which they were studied randomly with chance envelope.

Settings and conduct

Investigation applied on the first time pregnant patients with post term pregnancy conditions which they refer to the Besat hospital of Sanandaj. Also, they were Classified in two groups.

Participants/Inclusion and exclusion criteria

Gravid one post term pregnant women

Intervention groups

Gravid one post term pregnant women. For induction treatment In group No.01 oxytosin has been used. For induction treatment In group No.02 early amniotomy add to oxytosin.

Main outcome variables

The time of the stage one of labor; The time of the stage two of labor; One minutes apgar of newborn; Five minutes apgar of newborn

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180830040908N1**

Registration date: **2018-12-02, 1397/09/11**

Registration timing: **retrospective**

Last update: **2018-12-02, 1397/09/11**

Update count: **0**

Registration date

2018-12-02, 1397/09/11

Registrant information

Name

Ameneh Khalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3356 1977

Email address

amenehkhalili@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of labor outcome in induction with and without early amniotomy in nulliparous pregnant women with gestational age of 41 weeks and more

Public title

evaluation of early amniotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

gravid one pregnant with gestational age of 41 and more

Exclusion criteria:

indication of cesarean such as non cephalic presentation

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Actual sample size reached: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

All of the participants will stay on in two groups, randomly (chance envelope).

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 Kurdistan University of Medical Sciences

Street address

Pasdaran Blvd.,Kurdistan University Of Medical Sciences, Sanandaj, Iran.

City

Sanandaj

Province

Kurdistan

Postal code

6618634683

Approval date

2017-06-22, 1396/04/01

Ethics committee reference number

IR.MUK.REC.1396/331

Health conditions studied

1

Description of health condition studied

early amniotomy, post-term pregnancy.

ICD-10 code

O48.0

ICD-10 code description

Post-term pregnancy

Primary outcomes

1

Description

the total time of the active phase of labor

Timepoint

from the active phase of labor to fetus evoking

Method of measurement

questionnaire and stopwatch

Secondary outcomes

1

Description

infantal apgar, corio amnionitis

Timepoint

the 1st and 5th second after the labor- to 24 hr after the labor

Method of measurement

apgar score- fever measurements and investigation of the signs of corio amnionitis

Intervention groups

1

Description

Control group: 80 case study of gravid 1 pregnant patients with post pregnancy were studied, randomly (chance envelope). When bishop score reached to 5, oxytosin added for agmentation of labor. Then, the total time of the labor, one and five minute apgar investigated.

Category

Treatment - Drugs

2

Description

Intervention group: 80 case study of gravid 1 pregnant patients with post pregnancy were studied, randomly (chance envelope). When bishop score reached to 5, oxytosin added for agmentation of labor. Early amniotomy added, too. Then, the total time of the labor, one and five minute apgar investigated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Ameneh Khalili

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Dr Farnaz Zand Vakili

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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

Sanandaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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**

Sanandaj University of Medical Sciences

Full name of responsible person

Ameneh Khalili

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

only main Consequences

When the data will become available and for how long

start from 1398

To whom data/document is available

only researcher in academic centers and universities

Under which criteria data/document could be used

for more research in this field

From where data/document is obtainable

the E-mail address of the researcher

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

the E-mail address of the researcher

Comments