Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 garvid one post term pregnant conditions, were Classificated 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 Classificated in two groups.

Participants/Inclusion and exclusion criteria
Garvid one post term pregnant women

Intervention groups
Garvid 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)

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+98 87 3356 1977

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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
Street address
Pasdaran Blvd, Kurdistan University Of Medical Sciences, Sanandaj, Iran
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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
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Person responsible for updating data

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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