Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of maternal and neonatal outcome in three techniques: cephalic, breech and anterior shoulder used to deliver a deeply impacted fetal head during cesarean section

Protocol summary

Study aim

Comparison of maternal and neonatal outcome in three techniques:cephalic, breech and anterior shoulder used to deliver a deeply impacted fetal head during cesarean section

Design

Clinical trial with control group and parallel groups, randomized and single blind, conducted on 111 patients

Settings and conduct

This study is performed on 111 pregnant women referring to Ommol Banin Hospital in Mashhad. Patients are divided into three groups. In the first group, the fetus is dislodged by pushing its head. In the second group, the fetus is dislodged through pulling its legs, and in the third group, the fetus is dislodged using the anterior shoulder technique. In this single blind study outcome assessors are unaware of the type of grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria; term pregnancy, fetal head is at station zero or higher, cessation of labor due to impacted fetal head. Exclusion criteria: patients for whom the fetus does not rotate in the first stage of dilation

Intervention groups

In the intervention group, cesarean section is performed through the anterior shoulder technique. In the first control group, during the cesarean section, the fetus is dislodged through pushing the fetal head and in the second control group, the fetus is dislodged through pulling its legs.

Main outcome variables

Duration of surgery, bleeding volume during cesarean section, need for blood transfusion, length of hospital stay, apgar score of the newborn, the need to be hospitalized in neonatal intensive care unit (NICU)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201006048949N2**
Registration date: **2022-01-01, 1400/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-01, 1400/10/11**
Update count: **0**

Registration date

2022-01-01, 1400/10/11

Registrant information

Name

Azimeh Golzar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3727 9757

Email address

golzarta961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-16, 1400/07/24

Expected recruitment end date

2022-01-14, 1400/10/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of maternal and neonatal outcome in three techniques: cephalic, breech and anterior shoulder used to deliver a deeply impacted fetal head during cesarean section

Public title
Comparison of maternal and neonatal fate of fetal cesarean method

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Term pregnancy Fetal head is at station zero or higher Cessation of labor due to impacted fetal head

Exclusion criteria:
Patients for whom the fetus does not rotate in the first stage of dilation.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **111**

Randomization (investigator's opinion)
Randomized

Randomization description
The envelopes will be prepared by one of the members of the research team and the random numbers generated by the ''www.randomization.com'' website will be printed and placed in each envelope. In this website, the number of participants along with the number of groups are entered. Then for each group, a number of codes will be generated randomly. The envelopes are sealed and their contents are not visible from outside. At first, purpose of the study is explained for each participants and after filling out the consent form, each participant selects an envelope and opens it and based on its content, the participant will be placed in either the intervention or one of the control groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study only outcome assessors, when evaluating the patients, will be unaware of how patients are grouped and which treatment they receive.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Mashhad, University St., Mashhad University of Medical Sciences, Vice Chancellor for Research, Mashhad University of Medical Sciences

City
Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Approval date
2020-07-15, 1399/04/25

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.251

Health conditions studied

1

Description of health condition studied
Fetal cesarean section

ICD-10 code
O63.1

ICD-10 code description
Prolonged second stage (of labor)

Primary outcomes

1

Description
Duration of surgery

Timepoint
During childbirth

Method of measurement
Observation and examination

2

Description
Bleeding volume during cesarean section

Timepoint
During labor and up to 24 hours after labor

Method of measurement
Based on a checklist which includes counting the number of gauzes and long gauzes during cesarean section and hemoglobin level 24 hours after delivery

3

Description
Need for blood transfusion

Timepoint
During surgery

Method of measurement
Counting the number of gauzes which have absorbed blood and the amount of blood inside the suction

4

Description
Length of hospital stay
Timepoint
From admission to discharge
Method of measurement
Number of days of hospital stay

5

Description
Apgar score of the newborn
Timepoint
Minute 1 and 5 after birth
Method of measurement
Examination

6

Description
The need to be hospitalized in neonatal intensive care unit (NICU)
Timepoint
After childbirth
Method of measurement
Based on Apgar score

Secondary outcomes

1

Description
Need for hysterectomy or urinary tract surgery
Timepoint
Examination during childbirth
Method of measurement
observation

Intervention groups

1

Description
Control group: In this group during cesarean section, the fetal head faces down towards the mother's vagina. Using the push technique, the fetal head is dislodged by pushing it through the vagina.
Category
Treatment - Surgery

2

Description
Control group: In this group during cesarean section, the fetal buttocks are closer to the birth canal and the fetal head is up. Using the pulling technique, the fetus is dislodged by pulling its legs.
Category
Treatment - Surgery

3

Description
Intervention group: In this group during cesarean section, the anterior shoulder technique is used to deliver a deeply impacted fetal head. In this technique, at first, the fetal shoulder and body and then, the fetal head are dislodged.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Umm Al-Banin Hospital
Full name of responsible person
Farideh Akhlaghi
Street address
Zarrineh Crossroads - Ayatollah Behjat Street
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Province
Razavi Khorasan
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9144734756
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Akhlaghif@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mr Tafaghodi
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Mashhad, University Street, Mashhad University of Medical Sciences
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ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Farideh Akhlaghi

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

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Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Email
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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
All data can be shared after patients are made unidentifiable.

When the data will become available and for how long
Data can be accessible 6 months after results are published.

To whom data/document is available
Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used
Carrying out analysis on data is permitted.

From where data/document is obtainable
Data can be accessible through an email to the

corresponding author.

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

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments