

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two methods of prophylactic dislodge with routine cesarean indescending arrest

Protocol summary

Study aim

Comparison of neonatal and maternal outcomes associated with head-pushing and head-pulling methods for impacted fetal head extraction during cesarean delivery

Design

A clinical trial, with two intervention and control groups, One blind, randomized, 70 patients who are candidates for cesarean section will be included in this study

Settings and conduct

After the approval of the Ethics Committee of the Vice-Chancellor of Research of Tabriz University of Medical Sciences and registering at IRCT and obtaining consent from patients. 70 women with term pregnancy that they are candidates for cesarean section because of the onset of descending during labor. The patient will not be aware of which group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All women with singleton pregnancy and term gestational age who have fallen in the active phase of labor and give informed constant for our research. The exclusion criteria :multiple pregnancies; previous cesarean delivery; fetal anomalies and premature delivery.

Intervention groups

In the intervention group (35 people), an assistant helped to dislodge the head vaginally, and the surgeon delivered the dislodged head through the uterine incision; the rest of the fetus was delivered via routine cesarean techniques. In the pull (reverse breech) group, the surgeon inserted their hand toward the upper segment of the uterus and searched for the fetal leg; gentle traction was then applied until the second leg appeared. While holding both legs, the surgeon gently pulled the fetus up and out of the uterus through the uterine incision—similar to an assisted vaginal breech delivery. In the control group (35 people), the surgeon will try, take out the embryo, without doing dysluch. If the removal of the fetus during the above process is not

possible, then the head pushing method will be used.

Main outcome variables

Newborn apgar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180227038879N2**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

Registration date

2018-05-29, 1397/03/08

Registrant information

Name

Fatemeh Abbasalizadehf

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3553 9161

Email address

abbasalizadehf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-30, 1397/02/10

Expected recruitment end date

2019-01-30, 1397/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of two methods of prophylactic dislodge with routine cesarean indescending arrest

Public title
Comparison of two methods of prophylactic dislodge with routine cesarean indescending arrest

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Complete cervical dilatation Arrest descent for more than an hour The position of the fetus in a positive state of one
Exclusion criteria:
 Multiple pregnancies cesarean history Embryonic abnormalities

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients with using a random number table based on the case number, will be randomly assigned into two intervention and control groups

Blinding (investigator's opinion)
Single blinded

Blinding description
For all 70 patients, the study process will be explained, but the patients will not know which group will be studied.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Approval date

2018-04-16, 1397/01/27

Ethics committee reference number

IR.TBZMED.REC.1397.014

Health conditions studied

1

Description of health condition studied

Single delivery by cesarean section

ICD-10 code

082

ICD-10 code description

Single delivery by cesarean section

Primary outcomes

1

Description

Prevalence of fever in the mother

Timepoint

4 hours after delivery until discharge

Method of measurement

Thermometer

Secondary outcomes

1

Description

Apgar

Timepoint

Immediately after birth

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: The patient is placed in the lithotomy and after the transverse section of the lower segment of the womb by the surgeon and before acting to remove the head of the embryo, with the help of the surgeon, pressing on the head will be prophylactic in all cases. The surgeon will help the surgeon to push The head of the embryo is placed between the legs of the patient and with a zero degree of degree of pressure on the head of the embryo to a degree that causes displacement of the

head of the fetus.
Category
Treatment - Other

2

Description
Control group: Dislodge will not be used unless the surgeon recognizes it.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Fatemeh Abbasalizadeh
Street address
Alzahra Hospital, South Artesh St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research,Tabriz University Of Medical Sciences
Full name of responsible person
Abolghasem Juiban
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
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5138665793
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lahroudin@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for Research,Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Fatemeh Abbasalizadeh
Position
Professor Obstetricians and Gynecologists
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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