

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the maternal and neonatal fate of head removal between three methods of removing the head by the cephalic, breech, and anterior shoulder in the head deeply stuck in the pelvis

Protocol summary

Study aim

Comparison of maternal and neonatal complications of head removal between three methods of cephalic (push), pull (pull) and anterior shoulder resection in the head deeply stuck in the pelvis

Design

A clinical trial with three factorial groups on 111 people (three groups of 37 people) will use ANOVA test to compare quantitative variables between the three groups in case of normal distribution of data and Kruskal-Wallis test will be used otherwise.

Settings and conduct

In three groups of 37 people, in the first group, one fetus was removed by pushing the head and cephalic, in the second group, two fetuses were removed by pulling the legs and breeches, and in the third group, the anterior shoulder was removed. In three groups, the duration of surgery from skin incision to suturing, the amount of bleeding during cesarean section, intraoperative complications including enlarged incision, bladder trauma, uterine rupture, neonatal appendix, neonatal trauma, need for NICU hospitalization, and duration Wu's mother is hospitalized and compared. Location of Imam Reza Hospital

Participants/Inclusion and exclusion criteria

Complete Cervical effacement and Stop childbirth The head is stuck in the birth canal Station 1- or more

Intervention groups

In one group, the fetus is removed by pushing the head and cephalic, in one group, the fetus is removed by pulling the legs and breeches, and in the third method, by removing the anterior shoulder.

Main outcome variables

Duration of surgery, the extent of trauma to the bladder, trauma to the pelvic organs, volume of bleeding during cesarean section, an extension of uterine incision, involvement of uterine arteries, need for blood

transfusion, length of hospital stay, apkarnozad, trauma to the baby's organs, need for hospitalization Infant NICU, duration of infant hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N43**

Registration date: **2021-11-30, 1400/09/09**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-30, 1400/09/09**

Update count: **0**

Registration date

2021-11-30, 1400/09/09

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the maternal and neonatal fate of head removal between three methods of removing the head by the cephalic, breech, and anterior shoulder in the head deeply stuck in the pelvis

Public title

Comparison of the maternal and neonatal fate

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Complete Cervical effacement and Stop childbirth The head is stuck in the birth canal Station 1- or more

Exclusion criteria:

Fetal head does not come out of the birth canal in one of three ways

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 111

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Mashhad University of Medical Science

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

mashhad

Province

Razavi Khorasan

Postal code

9117699199

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**

Three methods of delivery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Duration of surgery

Timepoint

During surgery

Method of measurement

The duration of surgery is taken in three groups

2**Description**

The rate of bladder trauma

Timepoint

During the operation

Method of measurement

Trauma to the bladder is measured during surgery from skin incision to suturing

3**Description**

The degree of trauma to the pelvic organs

Timepoint

During the operation

Method of measurement

During surgery, from the incision of the skin to the suturing of the skin, the amount of trauma to the pelvic organs is measured

4**Description**

Bleeding volume during cesarean section

Timepoint

During the operation

Method of measurement

Bleeding is measured during surgery from skin incision to suturing

5

Description

Extension of uterine incision

Timepoint

During the operation

Method of measurement

During surgery, from the incision of the skin to the suturing of the skin, the extent of extension of the uterine incision is measured

6

Description

Uterine vascular involvement

Timepoint

During the operation

Method of measurement

Uterine vascular involvement is measured during surgery from skin incision to suturing

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

After surgery

Method of measurement

The length of hospital stay is taken

2

Description

Trauma to the baby's limbs

Timepoint

After surgery

Method of measurement

The extent of trauma to the baby's limbs is assessed

3

Description

Duration of hospitalization of the baby

Timepoint

After surgery

Method of measurement

The length of the baby's hospital stay is taken

Intervention groups

1

Description

In group one, the fetus is removed by pushing the head and cephalic. Neonatal trauma, the need for hospitalization at the NICU, and the length of time the mother and baby are hospitalized are compared and compared.

Category

Diagnosis

2

Description

In group two, we remove the embryos by pulling the legs and breeches. The duration of surgery from skin incision to skin suturing, the amount of bleeding during cesarean section, intraoperative complications including enlarged incision, bladder trauma, uterine artery rupture, neonatal apical Neonatal trauma, the need for NICU hospitalization, and the length of time the mother and baby are hospitalized are compared and compared.

Category

Diagnosis

3

Description

Intervention group: In the third group, we remove the fetus by removing the anterior shoulder. The amount of surgery from skin incision to suturing the skin, the amount of bleeding during cesarean section, intraoperative complications including enlarged incision, bladder trauma, uterine artery rupture, Infant apnea, neonatal trauma, the need for NICU hospitalization, and the length of time the mother and baby are hospitalized are compared and compared.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommolbanin Hospital

Full name of responsible person

Farideh Akhlaghi

Street address

Razavi Khorasan Province, Mashhad, Ayatollah Bahjat St,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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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

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

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Name of organization / entity

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Full name of responsible person

Farideh Akhlaghi

Position

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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