Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The effect of delayed umbilical cord clamping in term cesarean delivery on the mother and child's short-term outcomes

Protocol summary

Study aim

The effect of delayed umbilical cord clamping in term cesarean delivery on the mother and child's short-term outcomes .

Design

A randomized clinical trial, with two parallel arms, a blind, randomized phase 3 will be conducted on 118 women candidates for elective cesarean section. Eligible people will be selected during hospitalization in the delivery room using the available method and then will be assigned to two intervention and control groups using a random block of 4. Blocks of 4 will be generated using a table of random numbers.

Settings and conduct

The research population includes all eligible mothers undergoing elective cesarean section hospitalized in Ayatollah Mousavi Teaching Hospital, Zanjan will be assigned. In the present study, patients will be blind about the allocation of groups. In the intervention group, the umbilical cord of the baby during cesarean section will be one minute after birth. In the control group, the time of tying the umbilical cord will be immediately after the baby's birth.

Participants/Inclusion and exclusion criteria

Inclusion criteria Gestational age 37 to 41 weeks Candidate for caesarean section Singleton pregnancy Term pregnancy Exclusion criteria Having a high-risk pregnancy Emergency caesarean section Fetal distress Abnormalities of the fetus based on ultrasound Fetal growth restriction

Intervention groups

In the intervention group, the baby's umbilical cord will be clamped one minute after birth. In the control group, the time to tie the umbilical cord will be clamped immediately after the birth of the baby.

Main outcome variables

Hemoglobin; Hematocrit; Platelet ; Blood lost during the operation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230507058111N1**
Registration date: **2024-04-25, 1403/02/06**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-25, 1403/02/06**
Update count: **0**

Registration date

2024-04-25, 1403/02/06

Registrant information

Name

nassim ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3542 2706

Email address

nassimahmadi9458@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-19, 1403/01/31

Expected recruitment end date

2024-08-19, 1403/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of delayed umbilical cord clamping in term cesarean delivery on the mother and child's short-term outcomes

Public title
The effect of delayed umbilical cord clamping in term cesarean delivery on the mother and child's short-term outcomes
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age 37 to 47 Weeks Candidate for caesarean section Singleton pregnancy Term pregnancy
Exclusion criteria:
Having a high-risk pregnancy Emergency caesarean section Fetal distress Abnormalities of the fetus based on sonography Fetal growth restriction
Age
From **16 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **118**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible people will be assigned using convenience method during hospitalization in the delivery room. Blocks of 4 will be selected using a random number table so that the sample size reaches 59 people per each group. Blocking will be done by a person not involved in sampling.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, all patients will not know about the allocation of groups due to receiving anaesthesia for cesarean section.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zanjan University of Medical Sciences
Street address
Dr. Youssef Sobuti Blvd , Zanjan University of Medical Sciences, Zanjan
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Zanjan
Province
Zanjan
Postal code
4513956184
Approval date
2024-01-15, 1402/10/25
Ethics committee reference number
IR.ZUMS.REC.1402.239

Health conditions studied

1

Description of health condition studied
Delayed separation of umbilical cord
ICD-10 code
P96.82
ICD-10 code description
Delayed separation of umbilical cord

Primary outcomes

1

Description
Hemoglobin
Timepoint
Before the operation and 6 hours after the operation
Method of measurement
Laboratory

2

Description
Hematocrit
Timepoint
Before the operation and 6 hours after the operation
Method of measurement
Laboratory

3

Description
platelet
Timepoint
Before the operation and 6 hours after the operation
Method of measurement
Laboratory

4

Description
Average blood loss during cesarean section
Timepoint
After cesarean section

Method of measurement
The difference in the weight of gases used before and after cesarean section plus the amount of suctioned blood

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A group of mothers who undergo delayed umbilical cord clamping
Category
N/A

2

Description
Control group: A group of mothers who do not undergo delayed umbilical cord clamping
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Zanjan Hospital
Full name of responsible person
Behnaz Molaie
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Sponsors / Funding sources

1

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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Nassim Ahmadi
Position
Resident
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There are no plans for publication
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available