Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of two methods of sudden and delayed umbilical cord cramps on hemoglobin levels in preterm infants 34-30 weeks old born in Hajar Hospital, Shahrekord

Protocol summary

Study aim

The effect of umbilical cord clamp delay on hemoglobin in preterm infants under 34 weeks

Design

Clinical trial with control group, with parallel groups, double-blind, simple approved (last dance of mother file number) on102 infants.

Settings and conduct

In this study, pregnant mothers who referred for a normal delivery; They were randomly divided into two groups: umbilical cord ligation immediately up to 30 seconds after birth and umbilical cord ligation at 30-60 seconds after birth. The mothers were unaware of the group in which they were placed. In this study, the facilitator and the researcher were aware of the interventions and only the statistical consultant was not aware of the type of intervention of the groups. The course of labor of the subjects was controlled and in the second stage of labor, no manual pressure was applied on the cervix to assist labor. After delivery, the umbilical cord in the control group immediately up to 30 seconds after birth and in the intervention group between 30-60 seconds after birth and while the baby is in the arms of the delivery method, it is level with the mother's heart; Clamped and disconnected

Participants/Inclusion and exclusion criteria

Infants with a birth age of 30-34 weeks are admitted to the study with parental consent And infants in need of resuscitation immediately after birth and neonates born with twins and multiples and neonates born after traumatic and difficult births are excluded from the study.

Intervention groups

In the control group, the umbilical cord was clamped for less than 30 seconds and in the intervention group, the umbilical cord was clamped for 30 to 60 seconds.

Main outcome variables

Necrotizing enterocolitis Need oxygen Need phototherapy Duration of hospitalization Full feeding time PDA Hemoglobin level Apgar score

General information

Reason for update

Acronym

DCC

IRCT registration information

IRCT registration number: **IRCT20180915041040N4**
Registration date: **2021-04-12, 1400/01/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-12, 1400/01/23**
Update count: **0**

Registration date

2021-04-12, 1400/01/23

Registrant information

Name

Roya Choopani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

choopani.r@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-16, 1399/11/28

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of sudden and delayed umbilical cord cramps on hemoglobin levels in preterm infants 34-30 weeks old born in Hajar Hospital, Shahrekord

Public title

Delay umbilical cord clamping in premature infants

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Premature infants with GA 30-34 weeks age

Exclusion criteria:

The baby needs resuscitation immediately after birth Babies born with twins and multiples Babies born after a difficult and traumatic delivery

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization n this study, a table of random numbers is used. Infants with the right digit of the individual's maternal file number are in the control group (sudden umbilical cord clamp) and infants with the right digit of the pair of maternal file number are in the intervention group (delayed umbilical cord clamp).

Blinding (investigator's opinion)

Double blinded

Blinding description

En Parents of neonates and data analyzer and committee on safety and supervision of data were kept unaware of the groups their neonate was allocate to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Parastar

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815874119

Approval date

2021-02-15, 1399/11/27

Ethics committee reference number

IR.SKUMS.REC.1399.255

Health conditions studied

1

Description of health condition studied

Delay in cord clamping

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hemoglobin level 3 hours, 48 hours and 6 weeks after birth

Timepoint

3 hours, 48 hours and 6 weeks after birth

Method of measurement

Hours

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Delay in umbilical cord clamp - umbilical cord closure was performed at 30-60 seconds after birth and the hematocrit and hemoglobin level of the infant was determined at 3 and 48 hours after birth. The neonatal Apgar score is determined at the end of the first and fifth minutes and parameters such as the incidence of necrotizing enterocolitis, duration of oxygen requirement, duration of phototherapy, length of hospital stay, time of full feeding (milk intake at 120 cc / kg / d -100), and the frequency of PDAs is also recorded

Category

N/A

2

Description
Control group: Umbilical cord clamp immediately after birth - Umbilical cord clamping was performed up to 30 seconds after birth and the infant's hematocrit and hemoglobin levels were determined at 3 and 48 hours after birth. The neonatal Apgar score is determined at the end of the first and fifth minutes and parameters such as the incidence of necrotizing enterocolitis, duration of oxygen demand, duration of phototherapy, length of hospital stay, time of full feeding (milk intake at 100-120 cc / kg / day), and the frequency of PDAs is also recorded

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar Hospital

Full name of responsible person
Roya Choupani

Street address
Parastar

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
886854633

Phone
+98 38 3222 0016

Fax
+98 38 3224 3715

Email
choopani.r@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Dr Mehraban Sadeghi

Street address
Kashani

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Phone
+98 38 3224 2414

Email
vcrt@skums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Roya-choupani

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Parastar

City
Sharkord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8816854633

Phone
+98 38 3222 0016

Email
dr.choopani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Roya Choupani

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address

Parastar

City
Sharekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Phone
+98 38 3222 0016

Email
dr.choopani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Roya Choupani

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Parastar

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Phone
+98 38 3222 0016

Email
dr.choopani@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data is potentially shareable after unidentified individuals

When the data will become available and for how long
Access period starts from 1400

To whom data/document is available
It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
For use in future research only

From where data/document is obtainable
Applicants should contact the researcher at dr.choopani@yahoo.com or call 03832220016 ext.

What processes are involved for a request to access data/document
The researcher is obliged to provide the documents to the applicant as soon as possible after contacting the applicant or after correspondence by e-mail.

Comments