

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of the timing of umbilical cord clamping on hemoglobin levels and growth and developmental status in infants at 6 months old

Protocol summary

Study aim

The effect of the timing of umbilical cord clamping on hemoglobin levels and growth and developmental status in infants at 6 months old

Design

The clinical trial, with parallel groups, randomized, Double blind, single-center trial, sample size 60 people.

Settings and conduct

Amir Al-Momenin Hospital. The umbilical cord in both groups is closed and severed while the baby is in the arms at the same level as the vaginal opening during delivery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Newborns (37-40 weeks); Natural childbirth; Healthy and without any complications.
Exclusion criteria: Premature babies; Existence of congenital anomalies; Weight less than 2500 g and more than 4000 g; Twin babies.

Intervention groups

Intervention group: In this group, the umbilical cord of 51 newborns is clamped rate between 60 to 90 seconds after birth. Control group: In this group, the umbilical cord of 51 newborns is prematurely clamped in the first 20 seconds after birth and is only for comparison with the intervention group.

Main outcome variables

Hemoglobin level; Growth status.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N66**

Registration date: **2021-05-05, 1400/02/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-05, 1400/02/15**

Update count: **0**

Registration date

2021-05-05, 1400/02/15

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-08, 1400/01/19

Expected recruitment end date

2021-10-11, 1400/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the timing of umbilical cord clamping on hemoglobin levels and growth and developmental status in infants at 6 months old

Public title

The effect of the timing of umbilical cord clamping on growth and developmental status in infants at 6 months old

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Newborns (37-40 weeks) Natural childbirth Healthy and without any complications

Exclusion criteria:

Premature babies Existence of congenital anomalies
Weight less than 2500 g and more than 4000 g Twin babies

Age

From **259 days** old to **280 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

We will construct 6 blocks in AABB, BBAA, ABAB, BABA, ABBA, and BAAB using four blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 26 units of 4 blocks will be selected so that we consider having 51 people in the group (A) and 51 people in the group (B). Therefore, we will do block randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both participants and outcome assessors are unaware of the allocation of study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2021-02-27, 1399/12/09

Ethics committee reference number

IR.SEMUMS.REC.1400.005

Health conditions studied

1

Description of health condition studied

Umbilical cord

ICD-10 code

O69

ICD-10 code description

Labor and delivery complicated by umbilical cord complications

Primary outcomes

1

Description

Hemoglobin level

Timepoint

From birth to 6 months of age

Method of measurement

Blood test

2

Description

Growth status

Timepoint

From birth to 6 months of age

Method of measurement

Head height and circumference (cm) and weight (kg)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the umbilical cord of 51 newborns is clamped rate between 60 to 90 seconds after birth.

Category

Treatment - Other

2

Description

Control group: In this group, the umbilical cord of 51 newborns is prematurely clamped in the first 20 seconds after birth and is only for comparison with the intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital

Full name of responsible person

Mehri Ayati

Street address

Amir Al-Momenin Hospital, Mostafa Khomeini Blvd

City

Semnan

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3514799442

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are20935@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Mehri Ayati

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mehri Ayati

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Nazila Ameli

Position

Student

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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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

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

Undecided - It is not yet known if there will be 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