

# 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

**Province**

Semnan

**Postal code**

3514799442

**Phone**

+98 23 3345 1336

**Email**

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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Semnan University of Medical Sciences, Basij Blvd,  
Semnan.

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p\_kokha@yahoo.com

**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

**Street address**

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## Person responsible for scientific inquiries

### Contact

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**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