

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effect of time of umbilical cord clamping on hemoglobin concentration, newborn period and developmental process of infants up to 4 months age: a randomised controlled trial.

#### Protocol summary

##### Summary

The present research intends to carry out further and different follow-up studies on children with developmental disorders in their early years and determine factors related to incidence of developmental disorders in any community. Women without any history of medical and pregnancy problems and with 38-week pregnancy duration can enter the study. Moreover, breast-fed infants must be healthy with birth-time Apgar scores and weights of higher than seven and more than 2500 grams, respectively. Women with assisted birth (forceps and/or vacuum), prolonged labor, and/or complications such as bleeding and dystocia will be excluded from the research. This clinical trial research will be conducted on 400 pregnant women and their four-month old babies who visit the healthcare-treatment centers of Esfahan University of Medical Sciences and Healthcare Services in 2015 using the continuous sampling method. The women satisfying the inclusion criteria will be randomly divided into the intervention group with the umbilical cord clamped more than 90-120 seconds after birth and the control group in whom the umbilical cord is clamped less than 60 seconds after birth. Then, blood cord blood hemoglobin will be measured immediately after birth in both groups and The developmental status of infants in both groups at the age of 4 months will be evaluated using the ASQ questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201702066807N19**

Registration date: **2017-08-14, 1396/05/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-08-14, 1396/05/23

##### Registrant information

###### Name

Sedigheh Amir Ali Akbari

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2272 9240

###### Email address

akbarisedd@sbmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2015-05-05, 1394/02/15

##### Expected recruitment end date

2016-05-04, 1395/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of time of umbilical cord clamping on hemoglobin concentration, newborn period and developmental process of infants up to 4 months age: a randomised controlled trial.

##### Public title

The relationship between hemoglobin umbilical cord blood at birth and developmental status at 4 months age

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Iranian citizens, 18-35 years of age, given birth to four or fewer children, no history of known medical problems at present and during pregnancy such as diabetes, cardiovascular, renal, pulmonary or autoimmune diseases; no history of problems during pregnancy including preeclampsia, placental abruption, polyhydramnios; no history of known congenital abnormalities in the mother's or the husband's families; the recent childbirth without using forceps or vacuum; the recent delivery not a drawn-out one accompanied by complications such as bleeding and/or dystocia or by prolonged labor; pregnancy duration of exactly 38 weeks. Inclusion criteria for breast-fed infants: born in a single pregnancy; Apgar scores at birth not lower than seven; no history of reduced fetal growth; birth weight more than 2500 grams; healthy at their entry into the research (as confirmed by the physician at the center). Exclusion criteria: Inclusion criteria are not satisfied.

## Age

To 4 months old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 400

## Randomization (investigator's opinion)

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

Shahid Beheshti University of Medical Sciences

##### Street address

Vali Asr Ave, Niayesh Cross Road, School of Nursing & Midwifery

##### City

Tehran

##### Postal code

1985717443

## Approval date

2015-02-01, 1393/11/12

## Ethics committee reference number

sbmu.rec.1393.631

## Health conditions studied

### 1

#### Description of health condition studied

The amount of hemoglobin in the newborn's blood

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Hemoglobin

#### Timepoint

Immediately after birth

#### Method of measurement

Umbilical Cord Blood

### 2

#### Description

The development of infants

#### Timepoint

At the age of 4 months

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

complications of neonatal period (jaundice,infections,death,hospitalization)

#### Timepoint

4 months

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

The control group:Clamping the umbilical cord of newborns less than 60 seconds.

#### Category

Prevention

### 2

#### Description

Groups:Clamping the umbilical cord since birth 90-120

seconds  
**Category**  
Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Isa Ben Maryam Hospital  
**Full name of responsible person**  
Soheila Nouraei  
**Street address**  
**City**  
Esfahan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Mahrokh Dolatian  
**Street address**  
Vali Asr Ave, Niayesh Cross Road, School of Nursing & Midwifery  
**City**  
Tehran

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Shahid Beheshti University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

*empty*

### Domestic or foreign origin

*empty*

### Category of foreign source of funding

*empty*

### Country of origin

### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Seddigheh Amir Ali Akbari  
**Position**  
PHD  
**Other areas of specialty/work**  
**Street address**  
Vali Asr Ave, Niayesh Cross Road, school of Nursing &

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asa\_akbari@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences  
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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*