

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The delayed umbilical cord clamping effects on early outcome in Preterm neonates

Protocol summary

Broncho Pulmonary Dysplasia, Respiratory Distress Syndrome, Intra Ventricular Hemorrhage will be evaluate

Study aim

The effect of delayed umbilical cord clamp on early complications in premature infants

Design

Mothers were divided into 2 clammer groups in seconds 30 and 180 seconds using simple randomization and in parallel groups.

Settings and conduct

After the approval of the plan and the necessary coordination, all pregnant mothers who are eligible criteria will be given written consent after full explanation. Demographic and pregnancy data are entered from the case and pregnancy booklet and interviewed in a pre-filled questionnaire. Mothers are divided into 2 groups of clamps in seconds 30 and 180 seconds. After delivery and clamping of the patients in terms of neonatal blood parameters, weaning from ventilator, NICU discharge time, need for surfactant and neonatal complications including Cerebral Palsy, Retinopathy Of Prematurity, Broncho Pulmonary Dysplasia, Respiratory Distress Syndrome, Intra Ventricular Hemorrhage will be evaluate. Finally, after collecting the data, we provide them with a statistical expert for analysis.

Participants/Inclusion and exclusion criteria

Pregnant women with preterm pregnancy (28 to 37 weeks) exclusion criteria: The presence of underlying maternal disease such as preeclampsia, diabetes, blood disorders, heart disease Hemoglobin less than 11 bleeding due to Premature separation of placenta more than one fetus

Intervention groups

Mothers are divided into 2 groups of clamps in seconds 30 and 180 seconds.

Main outcome variables

After delivery and clamping of the patients , blood parameters, weaning from ventilator, NICU discharge time, need for surfactant and neonatal complications including Cerebral Palsy, Retinopathy Of Prematurity,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141208020249N2**

Registration date: **2018-07-01, 1397/04/10**

Registration timing: **retrospective**

Last update: **2018-07-01, 1397/04/10**

Update count: **0**

Registration date

2018-07-01, 1397/04/10

Registrant information

Name

Behzad Khalafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3344 9697

Email address

khalafi.behzad70@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-03-06, 1395/12/16

Actual recruitment end date

2018-03-20, 1396/12/29

Trial completion date

empty

Scientific title

The delayed umbilical cord clamping effects on early outcome in Preterm neonates

Public title

early outcome effects in delayed umbilical cord clamping

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

pregnant womens with preterm labor

Exclusion criteria:

Preeclampsia Diabetes Blood and coagulation Disorder

Heart Disease Hb under 11 mg/dl Bleeding due to

Premature separation of placenta more than one fetus

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

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**

Ethics committee of Kurdistan University of Medical Sciences

Street address

pasdaran Blvd, opposite Shadi Hotel, Kurdistan University of Medical Sciences, Sanandaj, Management of Medical Researches and Information. POB 6617713446

City

sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2017-03-04, 1395/12/14

Ethics committee reference number

IR.MUK.REC.1395/386

Health conditions studied**1****Description of health condition studied**

prematurity

ICD-10 code

P07

ICD-10 code description

Disorders of newborn related to short gestation and low birth weight, not elsewhere classified

Primary outcomes**1****Description**

Umbilical cord Clamping

Timepoint

180 and 30 second after birth

Method of measurement

chronometer

2**Description**

weaning from the ventilator

Timepoint

Until discharge or death

Method of measurement

Review the case file

3**Description**

discharge from ICU

Timepoint

Until discharge or death

Method of measurement

Review the case file

4**Description**

Neonatal complications

Timepoint

during the hospitalization

Method of measurement

Physical examination and paraclinical evaluations and case review

5**Description**

Need for surfactants
Timepoint
During the hospitalization
Method of measurement
Review the case file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Babies born to mothers with gestational age of 28 to 36 weeks of gestation

Category

Treatment - Other

2

Description

Control group: Babies born to mothers with gestational age of 28 to 36 weeks of gestation

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Nooshafarin Naderi

Street address

Vakil Crossroad, Besat Hospital, Department of Obstetrics and Gynecology

City

Sanandaj

Province

Kurdistan

Postal code

000000000000

Phone

+98 87 3328 2004

Email

naderi.nooshafarin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Farzin Rezaei

Street address

Sanandaj, Kurdistan University of Medical Sciences,

opposite Shadi Hotel, Kurdistan University of Medical Science, POB 6617713446 Management of medical research and information

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Phone

+98 87 3366 4645

Email

khalafi.behzad70@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Behzad Khalafi

Position

Research Associate / Researcher Soldier - General Physician of Kurdistan University of Medical Sciences

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Kurdistan University of Medical Sciences Vice Chancellor in Research Affair Pasdaran Ave. Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Phone

+98 45 3344 9697

Fax

+98 87 3366 4645

Email

khalafi.behzad70@muk.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Sholeh Shahgheibi

Position

Associate professor of Gny & Obs

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Vakil Crossroad, Besat Hospital, Department of Obstetrics and Gynecology

City

sanandaj

Province

Kurdistan

Postal code

0000000000

Phone

+98 87 3328 2004

Email

shahgheibi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Behzad Khalafi

Position

Researcher assistant

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

pasdaran Blvd, opposite Shadi Hotel, Kurdistan University of Medical Sciences, Sanandaj, Management of Medical Researches and Information. POB 6617713446

City

sanandaj

Province

Kurdistan

Postal code

6617713446

Phone

+98 87 3344 4645

Email

khalafi.behzad70@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is from the proposal, raw data and project reports

When the data will become available and for how long

Data is available from the legal system six months after publication for two years

To whom data/document is available

All persons will be able to access the Kurdistan University of Medical Sciences's request to the Kurdistan University of Medical Sciences.

Under which criteria data/document could be used

For legal issues and the need to use data in future studies

From where data/document is obtainable

Nooshafarin Naderi

What processes are involved for a request to access data/document

After submitting a request to the Kurdistan Research and Technology Dept. of Science and Technology, a call for submission is given.

Comments