

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jul 2026

### Study of the effectiveness of glycerin suppository on prevention of neonatal jaundice in neonatal

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of glycerin suppository on the prevention of neonatal jaundice

##### Design

Two parallel group of intervention and control that selected by random sampling and they were single-blinded in investigation of results.

##### Settings and conduct

Investigation was done in sanandaj besat hospital. In this hospital all neonates divided into two groups. Intervention group pushed by glycerin suppository 30 minutes after birth and repeated it after 12 hours again and 12,24,48 hours after birth bilirubin range checked by bilichex (ictrometer) and 5 days after birth called neonate's parents for their neonates follow up by checking bilirubin range by bilichex. Control group was not intervened with any suppository just checked their bilirubin range 12, 24, 48 hours after birth and also repeated their follow up 5 days after birth. Then all of the data for example first meconium defecation time, total bilirubin range collected by researcher.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : All of the neonates with gestational age between 37-42 weeks that born with NVD delivery  
Exclusion criteria: All of pathologic causes that make jaundice excluded from this study Weight under 2500g  
Born before 37week of gestational age Coombs positive  
Mismatch blood group Puerperal fever GDM  
Cephalohematoma Addicted mother Cesarean section type delivery

##### Intervention groups

Intervention group: all of the newborn neonates of besat hospital intervened by pushing the glycerin suppository in the neonates anal canal Control group: all of the newborn neonates without any intervention just evaluated by bilirubin range

##### Main outcome variables

bilirubin range

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180306038980N1**

Registration date: **2019-01-16, 1397/10/26**

Registration timing: **retrospective**

Last update: **2019-01-16, 1397/10/26**

Update count: **0**

##### Registration date

2019-01-16, 1397/10/26

##### Registrant information

##### Name

Rahmetulla Iri

##### Name of organization / entity

Kurdistan university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3217 8113

##### Email address

dr.iri76@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-07-23, 1396/05/01

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

2017-07-02, 1396/04/11

##### Actual recruitment end date

2017-12-22, 1396/10/01

##### Trial completion date

2017-12-22, 1396/10/01

## Scientific title

Study of the effectiveness of glycerin suppository on prevention of neonatal jaundice in neonatal

## Public title

Evaluation of Effect of glycerin suppository in prevention of neonatal jaundice in besat hospital in sanandaj in 2016-17

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

all of the newborn of besat hospital of sanandaj and referred newborn to that hospital

### Exclusion criteria:

under 2500 gr weight birth before 37th week of pregnancy positive combs ABO FEVER Fever GDM Cephalohematoma addicted mother c/s

## Age

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

## Gender

Both

## Phase

1

## Groups that have been masked

*No information*

## Sample size

Target sample size: **220**

Actual sample size reached: **210**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## 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 bvl.

##### City

sanandaj

##### Province

Golestan

##### Postal code

66177.13446

## Approval date

2017-03-06, 1395/12/16

## Ethics committee reference number

IR.MUK.REC.1395/387

## Health conditions studied

### 1

#### Description of health condition studied

neonatal jaundice

#### ICD-10 code

P59

#### ICD-10 code description

Neonatal jaundice from other and unspecified causes

## Primary outcomes

### 1

#### Description

Billirubin range

#### Timepoint

12,24 and 48 hours and 5 day after birth

#### Method of measurement

bilicheck instrument

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: all of the newborn neonates intervened by pushing turur anal canal by 1mg pediatrics glycerin suppository made by iran-najo factory at the birth time,12be and 24nd after birth and checked their bilirubin by Bolshevik 12,24,48be and 5 day after birth.

#### Category

Prevention

### 2

#### Description

Control group: All of the newborn neonates that they didn't push by glycerin suppository and but checked their bilirubin range by billicheck 12,24,48 hours and 5 day after birth.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

besat hospital of sanandaj

##### Full name of responsible person

rahmetulla iri

**Street address**

Besat hospital, Keshavarz ave. , Azadi square

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617713446

**Phone**

+98 87 3328 5910

**Email**

besathospital@muk.ac.ir

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Pediatrics department, besat hospitalT Kesahvarz ave. , azadi square

**City**

sanandaj

**Province**

Kurdistan

**Postal code**

besathospital@muk.ac

**Phone**

+98 33285910087

**Email**

dr.iri76@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

dr.farzin rezaei

**Street address**

pasdaran bvl. sanandaj

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617713446

**Phone**

+98 87 1666 4653

**Email**

info@muk.ac.ir

**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**

Majid Mansouri

**Position**

Associate professor

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Rahmetulla iri

**Position**

general practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

No.1, Enqelab 26 ave. ,enqelab town

**City**

Gorgan,

**Province**

Golestan

**Postal code**

4615685774

**Phone**

+98 17 3217 8113

**Email**

dr.iri76@gmail.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Rahmetulla iri

**Position**

general practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

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**Province**

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**Postal code**

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**Phone**

+98 17 3217 8113

**Email**

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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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

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

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Data of glycerin effect

**When the data will become available and for how long**

2018

**To whom data/document is available**

specialist

**Under which criteria data/document could be used**

for new intervention evaluation.رحمت الله

**From where data/document is obtainable**

rahmetulla iri

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

with Email or tel number

**Comments**