# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Study of the effectiveness of glycerin suppository on prevention of neonatal jundice 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 billirubin range checked by bilicheck (ictrometer) and 5 days after birth called neonate's parents for their neonates follow up by checking billirubin range by bilicheck. 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 Cesarian 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 new born neonates without any intervention just evaluated by billirubin 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 medicl 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 jundice 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 jundice
**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 newbirth 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 newbirth 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

## 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
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Pediatrics
**Street address**
Pediatrics department, besat hospitalT Kesahvarz ave. , azadi square
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## 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
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## Person responsible for updating data

**Contact**
**Name of organization / entity**
Sanandaj University of Medical Sciences
**Full name of responsible person**
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**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

## 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 evaulationرحمت الل
**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**