# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Preventive effects of purgative manna (vs. placebo) on neonate’s icter

### Protocol summary

**Summary**
The purpose of present study was to examine the preventive effects of purgative manna on neonate’s icter. It was a double blind clinical Trial study conducted among neonates who was born on Be’sat Hospital, Sanandaj, Iran. The sample size was 70 neonates in each group. . An inclusion criterion was being full term neonate and exclusion criteria were congenital anomalies and icter in day 1. Patients were divided into two groups using blocked randomization. Twenty four hours after birth, for three days, five drops of oral purgative manna drop (BiliNaster produced by Sobhan Co.) was given to intervention group three times a day, and placebo, produced by the same company, was given to infants in control group. Bilirobin and clinical evaluation for determining icter were measured during the third to fifth days.

### General information

**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT138901223666N2**
Registration date: **2010-11-26, 1389/09/05**
Registration timing: **retrospective**

Last update:
Update count: **0**
**Registration date**
2010-11-26, 1389/09/05

**Registrant information**
**Name**
Majid Mansoury
**Name of organization / entity**
Kurdistan University of medical sciences
**Country**
Iran (Islamic Republic of)
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+98 87 1324 7594
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**Recruitment status**
**Recruitment complete**
**Funding source**
Kurdistan University of medical sciences

**Expected recruitment start date**
2009-04-21, 1388/02/01
**Expected recruitment end date**
2010-01-20, 1388/10/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Preventive effects of purgative manna (vs. placebo) on neonate’s icter

**Public title**
Evaluation the preventive effects of purgative manna on neonate’s icter in Sanandaj, Iran
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
Inclusion criteria: Full term neonate. Exclusion criteria: Congenital anomalies, Icter in day 1
**Age**
From **1 year** old to **3 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **140**
**Randomization (investigator's opinion)**

Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Kurdistan University of medical sciences
**Street address**
Pasdaran Ave
**City**
Sanandaj
**Postal code**
**Approval date**
2009-04-13, 1388/01/24
**Ethics committee reference number**
3755 پ 14 پ

## Health conditions studied

### 1

**Description of health condition studied**
neonatal icterus
**ICD-10 code**
P59
**ICD-10 code description**
Neonatal jaundice from other and unspecified causes

## Primary outcomes

### 1

**Description**
Icterus
**Timepoint**
Day 3-5
**Method of measurement**
clinical examination and Lab exam

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention: Bilinaster drop produced by Sobhan Co. oral 5 drop/TDS (Twenty four hours after birth, for three days)
**Category**
Treatment - Drugs

### 2

**Description**
Control: Placebo drop produced by Sobhan Co. oral 5 drop/TDS
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Besat Hospital
**Full name of responsible person**
Majid Mansouri
**Street address**
**City**
Sanandaj

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Kurdistan University of medical sciences
**Full name of responsible person**
Dr Heidary
**Street address**
Pasdaran Ave
**City**
Sanandaj
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Kurdistan 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**
Kurdistan University of medical sciences

**Full name of responsible person**
Dr Majid Mansouri

**Position**
Fellow in neonatology

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**

**Other areas of specialty/work**

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**Web page address**

## 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*