

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy of oral agar gel administration on prevention of non hemolytic jaundice in normal term neonates; a double blind controlled trial

Protocol summary

Summary

In this study that will be done in Kerman medical university, neonatal ICU, we will assess the effect of oral agar gel in the prevention of non hemolytic jaundice in healthy and term neonates. In the first 24 hours of birth, bilirubin of 50 term neonates who their birth weight are more than 2500 grams and have no signs of infections or hemolytic disease is controlled with JM103 device in the form of transcutaneous measuring. Then, with regard to hyperbilirubinemia curve, those neonates who are in the risk of average or high hyperbilirubinemia are randomly divided into 2 groups of agar and placebo to receive either 500 mg of soluble agar in 2/5 cc aquapura or only aquapura every 6 hours. In the third and fifth day of birth, bilirubin is controlled in this way. In some cases that bilirubin is above physiologic range (13 mg/dl) bilirubin levels are checked by heel blood sampling too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811133250N1**

Registration date: **2010-04-24, 1389/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-24, 1389/02/04

Registrant information

Name

Bahareh Bahman Bijari

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1322 2250

Email address

bbbijari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Science

Expected recruitment start date

2009-12-22, 1388/10/01

Expected recruitment end date

2010-04-21, 1389/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of oral agar gel administration on prevention of non hemolytic jaundice in normal term neonates; a double blind controlled trial

Public title

Evaluation of the efficacy of oral agar gel administration on prevention of non hemolytic jaundice in normal term neonates; a double blind controlled trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: healthy, term infant with birth weight more than 2500 grams Exclusion criteria: Infants with infection, ABO or Rh incompatibility, G6PD deficiency and signs of lethargy or poor feeding

Age

To **1** year old

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**

Target sample size: 50

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 committees1**Ethics committee****Name of ethics committee**

Kerman University of Medical Sciences and Health Services

Street address

Jomhoori Blvd.

City

Kerman

Postal code**Approval date**

2010-02-08, 1388/11/19

Ethics committee reference number

K/88/232

Health conditions studied1**Description of health condition studied**

Neonatal jaundice

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes1**Description**

Serum bilirubin level

Timepoint

First day of life, third and 5th days of life after

intervention

Method of measurement

JM103- skin jaundicometer

Secondary outcomes

empty

Intervention groups1**Description**

Oral prescription of solution of 500 miligram of oral agar gel in 2.5 mililiter aquapura every 6 hours for 3 days

Category

Prevention

2**Description**

Oral prescription of 2.5 mililiter of aquapura every 6 hours for 3 days

Category

Placebo

Recruitment centers1**Recruitment center****Name of recruitment center**

Afzalipour hospital

Full name of responsible person

Leyla Razi

Street address

Afzalipour hospital, Imam Khomeini BLV

City

Kerman

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Kerman University of Medical Science

Full name of responsible person

Bahare Bahman Bijari

Street address

Kerman University of Medical Science

City

Kerman

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman University of Medical Science

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences and Health Services

Full name of responsible person

Bahareh Bahman Bijari

Position

Neonatologist

Other areas of specialty/work

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences and Health Services

Full name of responsible person

Bahareh Bahman Bijari

Position

Neonatologist-Assistant professor of Pediatrics

Other areas of specialty/work

Street address

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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