

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of oral agar gel on reduction of non-hemolytic jaundice intensity in term neonates

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Investigation the effect of oral agar gel on reduction of non-hemolytic jaundice intensity in term neonates

Design

Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 140 neonates with non-hemolytic jaundice.

Settings and conduct

This study will be conducted with the aim of investigation the effect of oral agar gel on reduction of non-hemolytic jaundice intensity in 140 term neonates. After inclusion in the study, using block randomization method with blocks of ten, the neonates will be assigned into two groups; intervention group receiving 500 mg agar in 2.5 cc of distilled water every 6 hours for 3 days and control group receiving only 2.5 cc of distilled water every 6 hours for 3 days. The neonates will be brought to pediatric clinic daily for 3 days and their jaundice will be measured by bili-check set and compared together in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being term; Breastfeeding; Birth weight more than 3000 grams; Having jaundice Exclusion criteria: Neonatal sepsis; Hemolytic jaundice

Intervention groups

Intervention group: Receiving 500 mg agar in 2.5 cc of distilled water every 6 hours for 3 days Control group: Receiving only 2.5 cc of distilled water every 6 hours for 3 days

Main outcome variables

Jaundice intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180724040580N1**

Registration date: **2018-08-20, 1397/05/29**

Last update: **2018-08-20, 1397/05/29**

Update count: **0**

Registration date

2018-08-20, 1397/05/29

Registrant information

Name

Bahram Lael Roodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 1000

Email address

b.laelroodi@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral agar gel on reduction of non-hemolytic jaundice intensity in term neonates

Public title

Effect of agar gel in jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being term Breastfeeding Birth weight more than 3000 grams Having jaundice

Exclusion criteria:

Neonatal sepsis Hemolytic jaundice

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with blocks of ten. Considering the sample size of 140, 14 blocks with 10 cards (5 cards for each group) will be selected; by selecting each block, 5 patients will be assigned into each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo will be coded as A and B and will be similar in shape so the patient and the caregiver (patient's physician) will be blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Asadabadi Ave, Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

lr.medsab.rec.1397.022

Health conditions studied

1

Description of health condition studied

Jaundice

ICD-10 code

P59

ICD-10 code description

Neonatal jaundice from other and unspecified causes

Primary outcomes

1

Description

Jaundice intensity

Timepoint

Daily

Method of measurement

Using Bili-Check set

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving 500 mg agar in 2.5 cc of distilled water every 6 hours for 3 days

Category

Treatment - Drugs

2

Description

Control group: Receiving only 2.5 cc of distilled water every 6 hours for 3 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmatie Hospital

Full name of responsible person

Bahram Lael Roodi

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Heshmatie Hospital, Asad Abadi street, Sabzevar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Dr. Fereshteh Ghorat
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Vice chancellor for research, Sabzevar University of
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Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Bahram Lael Roodi
Position
Medical Student
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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

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

make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable