

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of *Althaea rosea* batching on bilirubin levels of neonates with hyperbilirubinemia

Protocol summary

Study aim

Determining the effect of bath with marshmallow on bilirubin level of neonates with jaundice

Design

The infants who meet the inclusion criteria will be selected and then, by drawing lots and using even and odd numbers, 30 infants will be placed in the intervention group (phototherapy and bath with marshmallow) and 30 infants will be placed in the control group (phototherapy).

Settings and conduct

In the neonatal ward of Ali Ibn Abi Talib Hospital in Rafsanjan

Participants/Inclusion and exclusion criteria

1- Jaundice based on the doctor's diagnosis and serum total bilirubin 13 mg / dL and above 2- Do not suffer from underlying diseases 3- Total serum bilirubin 16 mg per deciliter and above 4- No ABO or RH incompatibility, no G6PD enzyme disorder and no positive Coombs test 5- Absence of physical anomalies in physical examination 6- Does not have any risk factors such as hemolysis, sepsis, asphyxia 7- No history of skin allergies in family members or any allergies to marshmallows 8- Term baby (over 38 weeks) 9- Weight over 2500 kg

Intervention groups

Grind 5 grams of marshmallow and put it in a liter of cold water for 8 hours, then add the extract in a liter of water with a temperature of 37 to 37.5, which is continuously measured by a thermometer. The room temperature is between -28. Set to 24 ° C. Before starting phototherapy, the infant is bathed with marshmallow once a day for 5 days (5 to 7 minutes) and the infant's body temperature is monitored again. Will be placed).

Main outcome variables

Change in bilirubin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210526051411N1**

Registration date: **2021-12-11, 1400/09/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-11, 1400/09/20**

Update count: **0**

Registration date

2021-12-11, 1400/09/20

Registrant information

Name

Neda Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3247 4440

Email address

neda.rahimi90@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of *Althaea rosea* batching on bilirubin levels of neonates with hyperbilirubinemia

Public title

Effect of Althaea rosea batching on bilirubin levels of neonates with hyperbilirubinemia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Jaundice based on the doctor's diagnosis and serum total bilirubin 13 mg / dL and above Do not suffer from underlying diseases Total serum bilirubin 16 mg per deciliter and above No ABO or RH incompatibility, no G6PD enzyme disorder and no positive Coombs test Absence of physical abnormalities in physical examination Does not have any risk factors such as hemolysis, sepsis, asphyxia No history of skin allergies in family members or any allergies to marshmallows Term baby (over 38 weeks) Weight over 2500 kg

Exclusion criteria:

Increased jaundice that requires blood transfusion Withdrawal of the baby's parents to continue participating in the research Discharge or death of the infant before the end of the intervention period The baby becomes ill during the course of the disease and during the study, which for any reason contradicts the intervention.

Age

From **1 day** old to **10 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, first, neonates with icterus whose disease is approved by a doctor and are admitted to the neonatal ward of Ali Ibn Abitaleb Hospital in Rafsanjan will be identified. Then, in order to randomly assign the infants to the phototherapy and phototherapy groups with a marshmallow bath, a coin toss (milk line) will be used. . The coin toss results are then recorded on a note sheet. The doctor will also start the treatment based on the results.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is two-blind so that both the baby's parents and the person collecting and analyzing the information of the type of intervention and in which group the baby is placed have no information. Newborns are admitted to different rooms.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Rafsanjan University of Medical Sciences

Street address

Nurse Street

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2020-11-28, 1399/09/08

Ethics committee reference number

IR.RUMS.REC.1399.201

Health conditions studied**1****Description of health condition studied**

jaundice

ICD-10 code

R17

ICD-10 code description

Unspecified jaundice

Primary outcomes**1****Description**

Bilirubin level

Timepoint

Before and after the study

Method of measurement

Photometry (by Juandice method)

Secondary outcomes

empty

Intervention groups**1****Description**

For the intervention group, grind 5 grams of Althaea officinalis and put it in one liter of cold water for 8 hours, then take the flower extract with a strainer and then take

the extract in a liter of water with a temperature of 37 to 37.5, which is continuously measured by a thermometer. we will add. The room temperature is also set between 28-24 ° C. At the beginning of admission and before the start of phototherapy, the baby is bathed with .The baby is bathed by *Althaea officinalis* a trained person. The hands are thoroughly washed before the intervention. The baby's body temperature is also measured by the Beurer GmbH digital thermometer made in Germany. The baby's body is washed step by step in 5 to 7 minutes. First, the neck area, especially the area behind the baby's ears, then the chest and upper limbs, abdomen and lower limbs, and finally the baby's back will be washed. At the end, the baby's body is dried with a clean, soft towel and the baby's body temperature is checked again, and the baby is placed under phototherapy with the XHZ model (one week before the sampling of the devices are calibrated). Once an hour, according to the routine of the neonatal serum bilirubin section, it is measured by photometric method (Juandice method in the accredited laboratory of the same hospital and is continuously entered in the data collection and registration form.

Category

N/A

2**Description**

Control group: In the control group, only phototherapy
Phototherapy with XHZ device is performed routinely

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Neonatal ward of Ali Ibn Abi Talib Hospital in
Rafsanjan

Full name of responsible person

Neda Rahimi

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Ali Ibn Abi Talib Street

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7717937555

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsizadeh

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7718796755

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alishamsy@gmail.com

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

Yes

Title of funding source

Rafsanjan 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**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Neda Rahimi

Position

Instructor of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Name of organization / entity

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neda.rahimi90@yahoo.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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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