Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 34 3247 4440

Email address
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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

Street address
Ali Ibn Abi Talib Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
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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 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
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