Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the Effects of Bathing with Cichorium intybus and Fumaria officinalis Water Extracts on the Icter Neonates

Protocol summary

Study aim
Comparing the Effects of Bathing with Cichorium intybus and Fumaria officinalis Water Extracts on the Icter Neonates

Design
A clinical trial with the control and intervention groups, with factorial groups, double-blind, randomized, phase 2-3 on 93 patients. A block randomization method was used for randomization.

Settings and conduct
After receiving the code of ethics and introduction letter, 93 Neonates from the neonatal department of Shahid Rahimi Medical Education Center in Khorramabad who are eligible to enter the study will be selected and divided into three intervention and control groups of 31 people (two intervention and one control).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Parents' willingness to participate in the study, the gestational age of the baby is 37 to 42 weeks, term babies with a weight of 2500 to 4000 grams without problems except for icter, Apgar 8 to 10 at birth, lactation and the onset of Icter after the second day, total serum bilirubin 14 to 20 mg/dL, the incidence of Icter in babies between 2 and 7 days, and hematocrit percentage greater than 65% or hemoglobin greater than 20. Non-entry criteria: congenital malformation or infection, need for blood transfusion, blood group incompatibility in baby and mother, having a history of skin allergies in the family, and hemolytic icter.

Intervention groups
The control group (with 31 neonates) received only phototherapy. The intervention groups (each with 31 neonates) will receive phototherapy and Bathing with Cichorium intybus and Fumaria officinalis extracts. The intervention will be done by washing from the face to the neck, especially the area behind the ears, chest and upper limbs, abdomen, lower limbs, and back.

Main outcome variables
Icter

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220706055388N2**
Registration date: **2023-06-27, 1402/04/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-27, 1402/04/06**
Update count: **0**

Registration date
2023-06-27, 1402/04/06

Registrant information

Name
Hanieh Goodarzi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 4261 0119

Email address
h.goodarzi100@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-26, 1402/04/05

Expected recruitment end date
2023-10-27, 1402/08/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the Effects of Bathing with Cichorium intybus and Fumaria officinalis Water Extracts on the Icter Neonates

Public title
Comparison of the effects of Bathing with Cichorium intybus and Fumaria Officinalis on Icter
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Parents' willingness to participate in the study The gestational age of the neonate is 37 to 42 weeks Term babies weighing 2500 to 4000 grams without problems except for icter Apgar 8 to 10 at birth Breastfeeding and the onset of jaundice after the second da Total serum bilirubin 14 to 20 mg/dL The occurrence of jaundice in babies between days 2 and 7 Hematocrit percentage greater than 65% or hemoglobin greater than 20
Exclusion criteria:
Congenital malformation or infection Need for blood transfusion Blood group incompatibility in baby and mother Having a history of skin allergy in the family Hemolytic icter
Age
From **2 days** old to **7 days** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **93**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocation of samples in groups will be done using the random block method. To equalize the distribution of the confounding variables of gender, birth weight, and gestational age, first classes based on these variables are described as girl/boy, weight less than 2500 grams/weight more than 2500 grams, and gestational age less than 37 weeks/37 weeks and above, and then they are balanced in the studied groups by the random block method. After that, they are divided into three groups (one control group and two intervention groups) in a simple random manner using a table of random numbers.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Khorramabad University of Medical Sciences ethics committee
Street address
No. 75, Azadi Alley, Palestine Cinema Alley, Ayatollah Kashani Street
City
Borujerd
Province
Lorestan
Postal code
6913718599
Approval date
2023-01-18, 1401/10/28
Ethics committee reference number
IR.LUMS.REC.1401.301

Health conditions studied

1

Description of health condition studied
jaundice
ICD-10 code
P59.8
ICD-10 code description
Neonatal jaundice from other specified causes

Primary outcomes

1

Description
Blood bilirubin level
Timepoint
Before the intervention, 24 and 48 hours after the intervention
Method of measurement
Arterial blood sample and sent to the laboratory

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention Group: This group will receive both phototherapy and bathing with Cichorium intybus extract. These Neonates were treated with sterile cotton before starting phototherapy and then for 2 days, once a day, after feeding at noon when phototherapy is stopped for health care and other cases, with 250 ml of Cichorium intybus extract. They bathe for 5 to 7 minutes. The room temperature is set at 24-28 degrees Celsius. Cichorium

intybus extract is also heated to a temperature of 37.5 degrees Celsius. (Cichorium intybus refers to the aqueous extract of the leaves of this plant. The preparation of the aqueous extract of this medicinal plant is done daily in the laboratory in accordance with the principles of extraction by the pharmaceutical chemist under the supervision of the project's pharmacist. 50 grams of ground Cichorium intybus in 250 cc of water The distillate is soaked at laboratory temperature for 72 hours away from sunlight. Then it is smoothed with Whatman filter paper and prepared for intervention in disposable bottles with a capacity of half a liter. The extracts are stored in the treatment room of the hospital wards at temperature properly maintained and used on a daily basis).

Category

Treatment - Drugs

2

Description

Second Intervention Group: This group will receive both phototherapy and bathing with Fumaria officinalis extract. These Neonates were first hospitalized using sterile cotton before starting phototherapy and then for 2 days, once a day, after feeding at noon, when phototherapy is stopped for health care and other cases, with 250 ml of Fumaria officinalis extract. They bathe for 5 to 7 minutes. The room temperature is set at 24-28 degrees Celsius. Fumaria officinalis refers to the aqueous extract of the leaves of this plant. The preparation of the aqueous extract of this medicinal plant is done daily in the laboratory by following the principles of extraction by a pharmaceutical chemist under the supervision of a project pharmacist. It is dried at room temperature and away from direct sunlight and is ground into powder using a mill. The powder obtained from Fumaria officinalis leaves is mixed with distilled water in a ratio of 1 to 9 (50 grams of powder in 450 cc of distilled water) and boiled for 10 to 15 minutes. Then the extract is filtered using Whatman paper and stored in colored glass until consumption.

Category

Treatment - Drugs

3

Description

Control Group: This group receives only phototherapy (single, double and intense). Being single, double and severe also depends on the Neonate's bilirubin level. Thus, the high bilirubin level receives a severe type. Before starting phototherapy, all Neonates are examined for Coombs, glucose-6-phosphate dehydrogenase, total and direct bilirubin levels, and mother's and Neonate's Rh blood group.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rahimi hospital

Full name of responsible person
Mansoureh Yousefian

Street address
Not Reaching Safavi Bridge., Mujahideen Ave., Azadi Square

City
Khorramabad

Province
Lorestan

Postal code
6813816314

Phone
+98 66 3333 6150

Email
rahimi@hospital.com

Web page address
http://hrgt.lums.ac.ir/tc

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Dr. Bahram Rasoulian

Street address
Zip code: 6813833946, Lorestan University of Medical Sciences Campus Complex, Anoushirvan Rezaei Sq, Moallem Ave, Khorram Abad, Iran

City
Khorram Abad

Province
Lorestan

Postal code
6813833946

Phone
+98 66 3330 0661

Email
publicrelation@lums.ac.ir

Web page address
http://www.lums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Khoram Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Hanieh Goodarzi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 75, Azadi Alley, Cinema Felestin Alley, Ayatollah Kashani Ave

City

Borujerd

Province

Lorestan

Postal code

6913718599

Phone

+98 66 4261 0119

Email

h.goodarzi100@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Hanieh Goodarzi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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