

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of oral use of pomegranate concentrated juice by mothers on hyperbilirubinemia in neonate under phototherapy

Protocol summary

Study aim

Evaluation of the effect of oral consumption of sweet pomegranate extract by mothers, in hyperbilirubinemia of infants under phototherapy

Design

Phase 3 randomized clinical trial with control group perform on mothers of 86 infants with hyperbilirubinemia. In both groups, phototherapy is performed with the same power. In the intervention group, in addition to phototherapy, mothers are given concentrated pomegranate extract. The serum level of total bilirubin in infants is measured daily to be discharged after reaching below 10mg/dl.

Settings and conduct

The mothers of 86 neonates who were hospitalized in Amirkola Children's Hospital enter to the study randomly and treated with phototherapy according to the protocol (bilirubin above 15 after the third day). Infants' blood bilirubin levels will be measured daily until discharge and will be compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers of hospitalized neonates for phototherapy with serum bilirubin level more than 15mg/dl. Exclusion criteria: Any illness or disorder in the mother or neonates that can interfere with the consumption of pomegranate extract.

Intervention groups

The intervention group includes mothers of infants with hyperbilirubinemia who, in addition to phototherapy, receive concentrated pomegranate extract. The control group includes mothers of infants with hyperbilirubinemia who receive only phototherapy.

Main outcome variables

neonate's blood bilirubin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046009N1**

Registration date: **2020-05-28, 1399/03/08**

Registration timing: **prospective**

Last update: **2020-05-28, 1399/03/08**

Update count: **0**

Registration date

2020-05-28, 1399/03/08

Registrant information

Name

Seyyed Ali Mozaffarpur

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral use of pomegranate concentrated juice by mothers on hyperbilirubinemia in neonate under phototherapy

Public title

Concentrated sweet pomegranate extract by breastfeeding mothers, in jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers of term infants (GA over 37 weeks) serum total bilirubin level of more than 15 mgr / dl over 48 hours of age breastfeed weighing more than 2,500 grams under phototherapy for the treatment of hyperbilirubinemia in the neonatal ward of Babol Shafizadeh Children's Hospital

Exclusion criteria:

Hemolytic disease (ABO, Rh incompatibility), G6PD deficiency in neonate Blood exchange in neonate Direct hyperbilirubinemia in neonate hyperbilirubinemia in neonate in the first 24 hours of life Systemic diseases such as liver, heart disease and hypothyroidism in neonate History of use of phenobarbital or other drugs or remedies in neonate sepsis in neonate respiratory distress in neonate Sensitivity to eating pomegranate juice in the mother

Age

From **3 days** old to **28 days** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by permuted blocks randomization. The size of the blocks is considered to be 4. (2 of each group in each block). Possible arrangements are made up of two groups (drug or control). Then, using the random number table, the numbers 1 to 6 (the number of possible arrangements) are selected and the order of groups of mothers is determined.

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

Ethics committee of Babol University of Medical Sciences

Street address

Sargord Ghasemi Ave

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2020-03-14, 1398/12/24

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.367

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

neonates bilirubin levels in blood

Timepoint

daily after hospitalization

Method of measurement

Bilirubin is checked by Diazo (photometric) method with Darman Faraz Kave kits made in Iran

Secondary outcomes

1

Description

The duration of phototherapy

Timepoint

The days of phototherapy for neonate

Method of measurement

The duration (days) of phototherapy

2

Description

the duration of hospitalization

Timepoint

the duration of hospitalization of neonates

Method of measurement

The duration (days) of phototherapy

3

Description

the need for blood transfusions

Timepoint

during hospitalization

Method of measurement

Is blood transfusions performed or not?

Fax

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seyyedali1357@gmail.com

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

Intervention group: Mothers of neonats with hyperbilirubinemia. After entering the study , concentrated pomegranate extract is used three times a day until hospitalization. Sweet pomegranates are bought in Behshahr region. The fruit species will be identified by the botanist of Nowshahr National Botanical Garden and a sample of it will be kept in the herbarium. The exact scientific name of the pomegranate species and the herbarium number will be obtained. Pomegranate will seed in hygienic condition, then pomegranate juice will be extracted so that the seed is not crushed. Then the pomegranate juice is condensed at a gentle temperature and in the Ben Marie device to some extent (Brix 70) to minimize the possibility of microbial contamination. After preparing the desired extract, microbial contamination control test will be performed and the necessary certificates will be obtained. Quality control tests are also performed for the extract, which includes the following measures: Measurement of water-soluble solids at 20 C (100% gram), pH and total acidity, total tannins, and determination of phenolic compounds in concentrated extract. Pomegranate by HPLC method

Category

Treatment - Drugs

2**Description**

Control group: Mothers of infants who receive only phototherapy

Category

Other

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

Babol School of Persian Medicine

Full name of responsible person

Hoda Shirafkan

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

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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

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Seyyed Ali Mozaffarpur

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

There is a plan to make this available on request

When the data will become available and for how long

After publication of the study, it will be available

To whom data/document is available

For every one who request, including reviewers of the manuscript

Under which criteria data/document could be used

for review articles

From where data/document is obtainable

for researchers and everyone who evaluates the results

What processes are involved for a request to access data/document

E mail to Dr. Mozaffarpur (seyyedali1357@gmail.com)

Comments