Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 15mgr/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

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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
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Babol
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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 (photometeric) 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?

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

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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
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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