

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The efficacy of pomegranate and plum pastes used in the last three months of pregnancy on exacerbated physiological neonatal jaundice in newborns: a double-blinded clinical trial

Protocol summary

Study aim

The efficacy of pomegranate and plum pastes used in the last month of pregnancy on exacerbated physiological neonatal jaundice in newborns in Afzalipour hospital, Kerman

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. Random sequence was used in SAS software for randomization.

Settings and conduct

The place of study is Afzalipour Hospital. Women in the 34th week of pregnancy are divided into 3 groups. A group receiving pomegranate paste in the last trimester of pregnancy, a group receiving plum paste in the last trimester of pregnancy, and the control group did not receive any treatment. The participants and the researcher who evaluates the results are unaware of the random allocation of participants.

Participants/Inclusion and exclusion criteria

Women in the 34th week of pregnancy, with a minimum age of 18 years and a maximum age of 35 years without a history of diseases such as hypertension, gestational diabetes and hypothyroidism.

Intervention groups

One group will receive pomegranate paste in the last trimester of pregnancy and one group will receive plum paste in the last trimester of pregnancy

Main outcome variables

Serum bilirubin level, frequency of receiving phototherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221023056271N1**

Registration date: **2022-12-05, 1401/09/14**

Registration timing: **prospective**

Last update: **2022-12-05, 1401/09/14**

Update count: **0**

Registration date

2022-12-05, 1401/09/14

Registrant information

Name

Maryam Dalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 8000

Email address

mar_dalili@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of pomegranate and plum pastes used in the last three months of pregnancy on exacerbated physiological neonatal jaundice in newborns: a double-

blinded clinical trial

Public title

The efficacy of pomegranate and plum pastes used in jaunsice

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

At least 18 years old Maximum age is 35 years

Exclusion criteria:

Mothers with gestational diabetes Mothers with hypertension Mothers with hypothyroidism History of severe jaundice in the last born baby History of blood transfusion in the last born baby Mothers with blood group O History of G6PD in last born baby

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use a random sequence created with SAS statistical software, women participating in the study will be divided into 3 groups based on the order of entering the hospital to receive services. Also, with the help of sealed transparent envelopes, random allocation will be concealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The pomegranate and plum pastes are presented to participants in both intervention groups in cloudy and nameless jars, and due to the similar taste of both substances, it is not possible to differentiate for the participants. Also, the researcher who collects, analyzes, and interprets the data does not know about allocation randomization.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Ethics committee of Kerman University of Medical Sciences, Afzalipour hospital, Imam highway, Kerman

City

Kerman

Province

Kerman

Postal code

7616913355

Approval date

2022-09-19, 1401/06/28

Ethics committee reference number

IR.KMU.AH.REC.1401.135

Health conditions studied

1

Description of health condition studied

Exacerbadated physiological neonatal jaundice in newborns

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Serum bilirubin level in newborns

Timepoint

Three days after birth

Method of measurement

Blood test

2

Description

Receive phototherapy

Timepoint

Three days after birth

Method of measurement

Doctor's diagnosis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: pomegranate paste, women in this group, during the last month of pregnancy, use pomegranate paste at the rate of one tablespoon twice a day for one month. They use it before food.

Category

Prevention

2

Description

Intervention group: plum paste, women in this group, during the last month of pregnancy, take one tablespoon of plum paste twice a day for one month. They use it before food.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Maryam Dalili

Street address

Afzalipour hospital, Imam highway, Kerman

City

Kerman

Province

Kerman

Postal code

7616913355

Phone

+98 34 3132 8000

Email

mar_dalili@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

Street address

Ebn-e Sina St., Vice-Chancellery for Research & Technology

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3226 3719

Email

malekpour@kmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Maryam Dalili

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Afzalipour hospital, Imam High way, Kerman

City

Kerman

Province

Kerman

Postal code

7616913355

Phone

+98 34 3132 8000

Fax

Email

Mar_dalili@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Maryam Dalili

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Afzalipour hospital, Imam High way, Kerman

City

Kerman

Province

Kerman

Postal code

7616913355

Phone
+98 34 3132 8000

Fax

Email
Mar_dalili@yahoo.com

+98 34 3132 8000

Fax

Email
Mar_dalili@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Maryam Dalili

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Afzalipour hospital, Imam High way, Kerman

City
Kerman

Province
Kerman

Postal code
7616913355

Phone

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