

# 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

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## 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