

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Investigating the effect of the educational package of Iranian medicine in the prevention of neonatal jaundice

Protocol summary

Study aim

Determining the effect of educational packages of Persian medicine in preventing neonatal jaundice in pregnant mothers

Design

A parallel Randomized clinical trial with a control group, on 100 pregnant women at 32 weeks of pregnancy. The randomization software was used for randomization.

Settings and conduct

This study will be carried out on pregnant women in the 32nd week of pregnancy after obtaining informed consent in Fasa health centers. Nutritional training includes the educational booklet of the Ministry of Health, which is suggested by the Iranian Medicine Group, which consists of a list of food recommendations to increase breast milk, which, in addition to being easier and cheaper to access, has more nutritional properties and its consumption is possible and valuable for most nursing mothers, and a list of foods that are effective in preventing infant jaundice.

Participants/Inclusion and exclusion criteria

inclusion conditions: women in the 32nd week of pregnancy, consent to participate in the study, not having an allergy to the recommended foods Exclusion conditions: lack of consent to participate in the study and lack of cooperation in the continuation of the study, sensitivity to the recommended foods

Intervention groups

The intervention group will receive training on special diet in person and in a package, and the control group will receive training on routine prenatal care. At the end of each week after the training, a food questionnaire that includes a list of recommended foods is asked and completed by the interviewers.

Main outcome variables

Neonatal jaundice; levels of bilirubin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230225057535N1**

Registration date: **2023-06-08, 1402/03/18**

Registration timing: **prospective**

Last update: **2023-06-08, 1402/03/18**

Update count: **0**

Registration date

2023-06-08, 1402/03/18

Registrant information

Name

Mahsa Rostami chijan

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3825 6275

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2024-08-05, 1403/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of the educational package of Iranian medicine in the prevention of neonatal jaundice

Public title

Studying the educational package based on Iranian medicine in the prevention of neonatal jaundice

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women in the 32nd week of pregnancy, consent to participate in the study, not having allergies to the recommended foods

Exclusion criteria:

Lack of consent to participate in the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

According to random allocation, participants will be assigned to two intervention and control groups. Random allocation is based on the block method. To use this method, after determining the sample size, which is 100 people, in step 1: according to the sample size of 100 and using the block size of 4, we need 25 blocks. After determining the permutation, which includes: AABB, ABAB, ABBA, and BAAB, We choose a random number from 1 to 24 to start allocating people in each block and the blocks will be selected similarly. and participants will be placed in randomized blocks. This method will be done with software.

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 Fasa University of Medical Sciences

Street address

Department of Persian Medicine, Fasa University of Medical Sciences, Ibn Sina Square,

City

Fasa

Province

Fars

Postal code

۷۴۶۱۶-۸۶۶۸۸

Approval date

2023-02-01, 1401/11/12

Ethics committee reference number

IR.FUMS.REC.1401.189

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

Comparison bilirubin levels in intervention and control groups on 3, 6, 9, 12,15, and 20 days after delivery.

Timepoint

Normal bilirubin level in newborns

Method of measurement

The blood sample of the newborn in the heel part of the intervention and control group will be taken by a trained nurse during 3, 6, 9, 12, 15, and 20 days after birth in the hospital, and bilirubin levels will be measured in the reference laboratory.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group: will receive trainings related to diet in person and in a package

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fasa University of Medical Sciences

Full name of responsible person

Elham Haghjoo

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Web page address<https://fums.ac.ir/>**Grant name**

Preventive and therapeutic recommendations of Iranian medicine in the treatment of neonatal jaundice

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Office of Iranian Medicine and supplement of the Ministry of Health

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**

Fasa University of Medical Sciences

Full name of responsible person

Elham Haghjoo

Position

assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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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