Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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
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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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Sponsors / Funding sources

1

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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
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Other areas of specialty/work
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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