

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluating the effectiveness of pregnant women's nutritional modification on neonatal jaundice

Protocol summary

Summary

Aims: Determining the Effectiveness of Nutritional Measures in Pregnant Women in Prevention of Neonatal Hyperbilirubinemia Design: Single blind interventional study (Only the participants) Setting and conduct: 80 pregnant women will be placed in equal numbers in two intervention and control groups. All of them should be healthy and free from underlying diseases (diabetes, high blood pressure and hypothyroidism) and give birth to healthy babies. The nutrition plan will be given to the intervention group. The neonatal blood bilirubin level will be measured 5 days after birth with bilirubin test. Major Inclusion criteria: Nulliparous pregnant women whose labor can be natural or Cesarean section; mothers with uncomplicated pregnancies; No history of systemic and chronic disease; willingness to cooperate in the study. Major Exclusion criteria: preterm delivery; complications of pregnancy such as gestational diabetes, pre eclampsia and hypothyroidism and high blood pressure; birth weight less than 2.5 or more than 4 kg; newborn infant with birth defects; less than 8 Apgar score; pathological jaundice. Interventions: (1) intervention group: not to use hot foods such as peppers, garlic, nuts, red meat and yolks from the 34th week of pregnancy + using cold foods such as yogurt, dough, lettuce, cucumber and watermelon if they feel warm in their body. (2) control group: No action. Main outcome measure: Jaundice in newborns

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017050933475N2**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Mohsen Manouchehrian

Name of organization / entity

Shahid Sadoughi University

Country

Iran (Islamic Republic of)

Phone

+98 21 4432 8882

Email address

m.manouchehrian@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of pregnant women's nutritional modification on neonatal jaundice

Public title

Interventional study of evaluating the effect of pregnant women's nutritional modification on neonatal jaundice

Purpose

Prevention

Inclusion/Exclusion criteria
 Inclusion criteria: Nulliparous pregnant women whose labor can be natural or Cesarean section; mothers with uncomplicated pregnancies; No history of systemic and chronic disease; willingness to cooperate in the study. Exclusion criteria: preterm delivery; complications of pregnancy such as gestational diabetes, pre eclampsia and hypothyroidism and high blood pressure; birth weight less than 2.5 or more than 4 kg; newborn infant with birth defects; less than 8 Apgar score; pathological jaundice.

Age
 No age limit

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **80**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 Randomization method: enclosed envelopes containing code

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Ethics committee of Iran University of Medical Sciences

Street address
 Next to the Milad Tower, Hemmat Highway

City
 Tehran

Postal code

Approval date
 2016-12-10, 1395/09/20

Ethics committee reference number
 IR.IUMS.REC 1395.95-03-208-29326

Health conditions studied

1

Description of health condition studied
 Pregnancy

ICD-10 code
 Z34

ICD-10 code description
 Supervision of normal pregnancy

Primary outcomes

1

Description
 The occurrence of jaundice

Timepoint
 4 days after birth

Method of measurement
 Bilirubin Test

Secondary outcomes

empty

Intervention groups

1

Description
 Intervention group: not to use hot foods such as peppers, garlic, nuts, red meat and yolks from the 34th week of pregnancy + using cold foods such as yogurt, dough, lettuce, cucumber and watermelon if they feel warm in their body

Category
 Prevention

2

Description
 Control group: No action

Category
 Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
 Akbar Abadi Hospital

Full name of responsible person
 Dr. Mohsen Manouchehrian

Street address
 Akbar Abadi Hospital, Bagh Ferdos station, Molavi street.

City
 Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Iran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Kazem Malakooti

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Research Center of Akbar Abadi Hospital

Full name of responsible person

Dr. Mohsen Manouchehrian

Position

Resident of Traditional Medicine

Other areas of specialty/work

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Akbar Abadi Hospital, Bagh Ferdos Station, Molavi Street.

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Mohsen Manouchehrian

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty