Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of adding whey protein to the diet of nursing mothers in the first week after delivery in the prevention of severe physiologic jaundice in full term infant

Protocol summary

Study aim

Assessing the severity of physiological jaundice in term infants in the control group and the intervention group Comparing of the severity of physiological jaundice in term infants in two groups

Design

The clinical trial consists of a control group and an intervention group. Sampling is non-random, convenience(available sample). Allocation of participants to two groups is performed using a randomized block design with RAS software. Each group consists of 50 participants, for a total of 100 participants.

Settings and conduct

Pregnant women in the last month of pregnancy who referred to the pregnancy clinic of Mahdieh Hospital were selected. The control group received their usual diet after delivery and recorded it daily. The intervention group consumed a serving of whey protein equivalent to 2 tablespoons in a glass of warm water in the morning on an empty stomach, and other nutritional items remained unchanged. The mother's daily diet was also recorded. The two groups were homogenized in terms of risk factors such as diabetes in the mother. Infants in both groups were followed up on the first day and the fifth day of birth for the occurrence of jaundice. Jaundice screening was performed by a nurse using a skin test.

Participants/Inclusion and exclusion criteria

Inclusion criteria: term newborns - Written consent from parents Non inclusion criteria: hospitalization of the infant on the first day of birth due to icterus

Intervention groups

The control group received their usual diet after delivery and recorded the diet plan daily. After delivery, the intervention group consumed a simple whey protein meal equivalent to 2 tablespoons in a glass of warm water in the morning on an empty stomach for 5 days. Their other nutritional sources remained unchanged and recorded the diet plan daily.

Main outcome variables

Skin bilirubin determination; Weighing the baby

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230618058522N1**
Registration date: **2023-12-01, 1402/09/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-01, 1402/09/10**
Update count: **0**

Registration date

2023-12-01, 1402/09/10

Registrant information

Name

Farzaneh Khosropour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5697 1068

Email address

khosropoor67@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-31, 1402/08/09

Expected recruitment end date

2024-04-28, 1403/02/09

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of adding whey protein to the diet of nursing mothers in the first week after delivery in the prevention of severe physiologic jaundice in full term infant

Public title
Investigating the effect of adding whey protein in the prevention of severe physiologic jaundice in full term infant
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy term newborns (gestational age more than 37 weeks) Written consent from parents
Exclusion criteria:
Hospitalization of the infant on the first day of birth due to icterus
Age
From **1 day** old to **1 day** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Shahid Beheshti University of Medical Sciences
Street address
No. 5, Unit 15, 4th Basirat Alley., Janbazan Blvd., Ghaemieh Town., Islamshahr
City
Tehran
Province
Tehran
Postal code
3315899308
Approval date
2023-06-02, 1402/03/12
Ethics committee reference number
IR.SBMU.MSP.REC.1402.093

Health conditions studied

1

Description of health condition studied
Neonatal physiological icterus
ICD-10 code
P59.9
ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
Bilirubin
Timepoint
Measurement of skin bilirubin on the first day of birth and 5 days after the intervention
Method of measurement
Standard skin bilirubin measurement device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The mother consumes a daily serving of simple whey protein equivalent to 2 tablespoons (20 grams) from Olida company in a glass of warm water in the morning on an empty stomach for 5 days after giving birth.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Hospital
Full name of responsible person
Farzaneh Khosropour
Street address
Shahid Borujerdi St., Shishegar Khaneh St., Fadayian

Islam St., Shush Square., Mahdieh Hospital
City
Tehran
Province
Tehran
Postal code
1185817311
Phone
+98 21 5506 2628
Email
mahdiyeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
5th Floor., Building No. 2, Shahid Arabi St., Yemen St., Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9780
Email
zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farzaneh Khosropour
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
No. 5., Unit 15., 4th Basirat Alley., Janbazan Blvd., Ghaemieh Town., Islamshahr
City
Tehran
Province
Tehran
Postal code
3315899308
Phone
+98 21 5697 1068
Fax
Email
khosropoor67@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farzaneh Khosropour
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
No. 5., Unit 15., 4th Basirat Alley., Janbazan Blvd., Ghaemieh Town., Islamshahr
City
Tehran
Province
Tehran
Postal code
3315899308
Phone
+98 21 5697 1068
Fax
Email
khosropoor67@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farzaneh Khosropour
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address

No. 5., Unit 15., 4th Basirat Alley., Janbazan Blvd., Ghaemieh Town., Islamshahr

City
Tehran

Province
Tehran

Postal code
3315899308

Phone
+98 21 5697 1068

Fax

Email
khosropoor67@sbmu.ac.ir

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