

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Mahdiah 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., Mahdiah Hospital

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Email

mahdiyeh_hospital@sbm.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

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Ghaemieh Town., Islamshahr

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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

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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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