Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of exclusive breast milk and breast milk with formula feed in incidence of Icter –admission and dehydration in term neonatal over 2500 gr

Protocol summary

Study aim
Comparison of breastfed infants with breast milk + infant formula during the first days of life in terms of infant jaundice(icter), dehydration and hospitalization of term infants weighing more than 2500 in Kowsar Hospital

Design
Clinical trial with control group, with parallel, randomized groups, on 118 patients. Excel software rand function was used for randomization.

Settings and conduct
The study was performed in Kosar Hospital in Qazvin in the first 4 months of 1401 on term infants weighing more than 2500 grams and less than ten days old who are close to their mother and breastfeeding is started and followed up to ten days.

Participants/Inclusion and exclusion criteria
In this study, all term infants weighing more than 2500 grams are included in the study Exclusion criteria: 1. Maternal dissatisfaction with formula feeding 2. Mothers who are unable to breastfeed their babies due to medical issues 3. Infants who need to be hospitalized at birth due to congenital diseases that have been identified before or during birth, etc.

Intervention groups
Term infants over 2500 grams and under ten days

Main outcome variables
Reduce the average length of hospital stay Baby weight loss Jaundice (neonatal jaundice)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210314050695N1**
Registration date: **2022-02-05, 1400/11/16**
Registration timing: **prospective**
Last update: **2022-02-05, 1400/11/16**
Update count: **0**

Registration date
2022-02-05, 1400/11/16

Registrant information

Name
Marziyeh Karimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3365 3199

Email address
m.karimi.681010@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2022-08-22, 1401/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of exclusive breast milk and breast milk with formula feed in incidence of Icter –admission and dehydration in term neonatal over 2500 gr

Public title
Study on the formula effect in the reduction of Icter admission

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

In this study, entrance criteria goes for all the infants holding more than 2500 grams weight

Exclusion criteria:

Dissatisfaction of mother to feed the infant with formula Mothers, whom can not breath feed their infants because of medical issues Infants, whom upon their birth require admission in hospital units because of their congenital disease (before or after the birth is diagnosed)

Age

From **2 days** old to **10 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **118**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization unit of randomization : individual tools of randomization : random numerical table Random number table is a set of numbers that are produced without a specific pattern or order and in a completely random manner and has become a table. In order to use the random number table, we must first preset the table to read the numbers (for example, up, down, left or right), the second assumption is to consider numbers for different groups, for example, even numbers for Group 1 intervention. And odd numbers for group 2 intervention

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 Qazvin University of Medical Sciences

Street address

Felestin Ave; Qods square ; Qods hospital

City

Qazvin

Province

Qazvin

Postal code

3415914595

Approval date

2020-10-24, 1399/08/03

Ethics committee reference number

99000049

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

Reduce hospitalization or non-hospitalization due to neonatal jaundice / prevent infant weight loss

Timepoint

Daily up to ten days

Method of measurement

tcb (transcutaneus bilirubinometer)

Secondary outcomes

empty

Intervention groups

1

Description

Control group:Infants who are exclusively breastfeed

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital

Full name of responsible person

Marziyeh Karimi

Street address

Kosar hospital ; taleghani Ave; Emam khomeini Ave;

City

Qazvin

Province

Qazvin

Postal code

3415613176

Phone

+98 28 3324 2452

Email
hoskosar@qums.ac.ir
Web page address
http://hoskosar.qums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mohamad mahdi Ememjome
Street address
Qods hospital; Qods square ; Felestin Ave;
City
Qazvin
Province
Qazvin
Postal code
3415914595
Phone
+98 28 3333 4807
Email
info@ghodshospital.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
marziyeh karimi
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
No . 17 fahim alley 4 , mosayeb moradi ave, nokhbegan blvd . qazvin town
City
qazvin
Province
Qazvin
Postal code
3414967888
Phone
+98 28 3365 3199
Email
m.karimi.681010@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
marziyeh karimi
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
qods hospital . qods squre , qazvin town
City
Qazvin
Province
Qazvin
Postal code
3414967888
Phone
+98 28 3365 3199
Email
m.krimi.681010@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
marziyeh karimi
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Qods children hospital
City
Qazvin
Province
Qazvin
Postal code
3415914595
Phone
+98 28 3333 4809
Email
m.karimi.681010@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentifiable individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
It will be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
In order to inform the general public and use in other texts and research
From where data/document is obtainable
Refer to Qazvin University of Medical Sciences Research and Development Center
What processes are involved for a request to access data/document
After referring to the research and development unit of Qazvin University of Medical Sciences and submitting a request for access to the data, they can follow up their application within the specified working time.
Comments