

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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 (transcutaneous 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**

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**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

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**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

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

marziyeh karimi

**Position**

Associate professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Email**

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## 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**