Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of phototherapy with probiotic + phototherapy alone in neonates with icter in Qazvin Kowsar Hospital

Protocol summary

Study aim

Comparison of the effect of phototherapy with phototherapy + probiotic in neonates with icter in Qazvin Kosar Hospital

Design

44 patients were studied. The first group received usual phototherapy + distilled water and the second group received 5 drops of Pedilact (probiotic) 2 times daily for 3 days in addition to phototherapy, and hospitalization and Bilirubin reduction rates based on gestational age and sex in both groups were compared.

Settings and conduct

Each group has 44 patients. Category The first group receives usual phototherapy + distilled water and the second group besides phototherapy, Pedilact drops (Probiotics) 5 drops, given 2 times a day in 3 days by the pediatric resident, The resident unconsciously gives the baby a pedilact drop or distilled water the pediatric resident not have any Information about which group of probiotic drop babies with phototherapy and which phototherapy group only This is done in the neonatal ward of Qazvin Kowsar Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Icteric neonates at Kosar Hospital who have no symptoms of Sepsis and respiratory distress are not admitted to the NICU and have no underlying disease.Exclusion criteria: Sepsis, respiratory distress and seizure, pre-term infants 35 weeks, for any reason that the infant becomes critically ill during examination and hospitalization.

Intervention groups

In one group, a probiotic (pedilact drop) study was performed to reduce neonatal jaundice given orally twice daily and five drops daily for three days with phototherapy at Kosar Hospital, the other group only had phototherapy to reduce jaundice.

Main outcome variables

The main variable is bilirubin. In this study the effect of probiotic on bilirubin is investigated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191022045194N1**
Registration date: **2020-03-29, 1399/01/10**
Registration timing: **prospective**

Last update: **2020-03-29, 1399/01/10**
Update count: **0**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name

Hanna Sanandaji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3334 4157

Email address

hanisndj@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of phototherapy with probiotic + phototherapy alone in neonates with icter in Qazvin Kowsar Hospital

Public title
Comparison of the effect of phototherapy with phototherapy + probiotics only in infants with icter
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria include: icteric neonates at Kosar Hospital who have no symptoms of Sepsis . Icteric neonates admitted to Kosar Hospital with no respiratory distress Icteric neonates hospitalized at Kosar Hospital who are not admitted to the NICU Icteric neonates admitted to Kosar Hospital with no underlying disease
Exclusion criteria:
Exclusion criteria: For any reason, the baby will be critically ill during the examination and hospitalization For whatever reason, the baby may develop respiratory distress For any reason, the baby may have seizures For whatever reason, the baby will receive medication
Age
From **2 days** old to **14 days** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
In each group, 44 patients were studied. The first group received usual phototherapy + distilled water and the second group received 5 drops of Pedilact (probiotic) 2 times daily for 3 days in addition to phototherapy, and hospitalization and Bili reduction rates based on gestational age and sex in both groups were compared. Can be. Also, the method of implementation is to inform the resident of the project by unconsciously examining the reduction of Bili in the two groups and not knowing which groups of probiotic drops infants receive phototherapy and which groups receive phototherapy alone.
Blinding (investigator's opinion)
Double blinded
Blinding description
In each group, 44 patients were studied. The first group received usual phototherapy + distilled water and the second group received 5 drops of Pedilact (probiotic) 2 times daily for 3 days in addition to phototherapy, and hospitalization and Bili reduction rates based on gestational age and sex in both groups were compared. Can be. Also, the method of implementation is to inform the resident of the project by unconsciously examining the reduction of Bili in the two groups and not knowing which groups of probiotic drops infants receive phototherapy and which groups receive phototherapy alone.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Qazvin University of Medical Science
Street address
Qods hospital,Qods sq,Shahidbeheshti Blvd
City
Qazvin
Province
Qazvin
Postal code
3415914595
Approval date
2019-05-28, 1398/03/07
Ethics committee reference number
IR.QUMS.REC.1398.041

Health conditions studied

1

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

Primary outcomes

1

Description
Bilirubin
Timepoint
one week
Method of measurement
Plasma Bilirubin Level

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Neonates who intake pedilact drop
Category
Treatment - Drugs

2

Description
Control group: Neonates who don not intake any drugs
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
Hanna Sanandaji
Street address
Qods hospital,Qods Square,Felestin st.
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3415914595
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Hanisndj@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mohammad Mahdi Emamjome
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Shahid Bahonar Blv.,Qazvin University of Medical Science
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Cgd_rc@yahoo.com
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
Morteza Habibi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

Contact

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Full name of responsible person
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Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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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
Undecided - It is not yet known if there will be 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
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

Title and more details about the data/document
Report data as an article

When the data will become available and for how long
After completing the sampling and analysis of the data interpretation, the information will be published as an article.

To whom data/document is available
In coordination with the supervisor of researchers working in academic institutions

Under which criteria data/document could be used
For writing meta-analysis articles

From where data/document is obtainable
Dr Morteza Habibi,Neonatal specialist .Address:Kowsar Hospital, Kowsar Avn, Khamenei Blvd ,Qazvin. Tel:982833236374 Dr Hanna Sanandaji,Pediatric resident.Address:Qods Hospital, Qods Sq, Shahid beheshti Blvd, Qazvin. Tel:98283334808

What processes are involved for a request to access data/document
Send a formal letter by email or to the address of the project

Comments