

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 Kowsar 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 Kowsar 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 Kowsar 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		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.	
Public title	Comparison of the effect of phototherapy with phototherapy + probiotics only in infants with icter	Placebo	Used
Purpose	Treatment	Assignment	Parallel
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	Other design features	
Age	From 2 days old to 14 days old	Secondary Ids	
Gender	Both	empty	
Phase	1-2	Ethics committees	
Groups that have been masked	- Participant - Care provider - Investigator	1	
Sample size	Target sample size: 88	Ethics committee	
Randomization (investigator's opinion)	Randomized	Name of ethics committee	
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.	Ethic committee of Qazvin University of Medical Science	
Blinding (investigator's opinion)	Double blinded	Street address	
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	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 icter	
		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.

City

Qazvin

Province

Qazvin

Postal code

3415914595

Phone

+98 28 3333 4807

Email

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

Street address

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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Kowsar hospital, kowsar Ave, Khamenei Blvd

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Person responsible for scientific inquiries

Contact

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Latest degree

Subspecialist

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Person responsible for updating data

Contact

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Medical doctor
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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