

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Therapeutic effects of Synbiotics plus phototherapy on decreasing bilirubin level in 3-14 day old icteric Neonates with gestational age >35 weeks and comparison with only phototherapy therapeutic effect

Protocol summary

Study aim

Our objective is evaluation of therapeutic effects of Synbiotics plus routine phototherapy on decreasing bilirubin and duration of admission and defecation numbers in term icteric neonates with > 35 weeks GA and compare the results with icteric neonates under routine phototherapy without Synbiotic administration.

Design

Our study is a randomized, double-blind trial. 194 neonates participate in our study (97 neonates in each group). The patients are randomly divided in to two groups through block randomization using blocks of size 4. Intervention group will be treated by 5 drops of pedilact in addition to daily phototherapy. Control group will be given 5 drops of placebo every day in addition to phototherapy. The level of bilirubin will be measured daily until the day of discharge. The frequency of defecation and any complication will be recorded.

Settings and conduct

Our double blind randomized study will be done at Rasht 17 Shahrivar hospital, after obtaining informed consent from parents. Patients and parents will be unaware of the type of prescribed drug.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Gestational age > 35 weeks; being at the age of 3-14 days; weight > 2500 gr; total Bilirubin between 15-22; exclusive breast feeding Exclusion criteria: Sepsis; underlying disease; diabetes in mother; treated by phenobarbital or bilinaster; family history of immune deficiency; treated by antibiotics.

Intervention groups

Intervention group will be treated with daily Synbiotic (Pedi-lact) oral drop and routine phototherapy. The control group will only receive phototherapy (without Synbiotics).

Main outcome variables

Bilirubin Level in Admission Day and Daily to

Discharge. Defecation Number and stool consistency
;Duration of Phototherapy And Admission.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180228038895N1**

Registration date: **2018-09-26, 1397/07/04**

Registration timing: **prospective**

Last update: **2018-09-26, 1397/07/04**

Update count: **0**

Registration date

2018-09-26, 1397/07/04

Registrant information

Name

Seyedeh Azadeh Hosseini Nouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9026

Email address

dr.azadehoseini@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-12, 1397/07/20

Expected recruitment end date

2019-10-12, 1398/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Therapeutic effects of Synbiotics plus phototherapy on decreasing bilirubin level in 3-14 day old icteric Neonates with gestational age >35 weeks and comparison with only phototherapy therapeutic effect

Public title
Effect of Synbiotics on Neonatal hyperbilirubinemia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 3-14 days Total bilirubin between 15-22 mg/dl and direct bill <1.5 Exclusive breast feeding Without underlying disease Weight>2500gr
Exclusion criteria:
 Sepsis Cephalhematoma ABO incompatibility G6PD deficiency Underlying disease Parental dissatisfaction Polycythemia RH incompatibility Formula feeding Treated by Phenobarbital .billinaster.etc... Transfer to NICU Down Syndrome Family history of Immune deficiency Blood exchange Treated by Antibiotics Serum therapy Hemolysis Diabetes in Mother

Age
From **3 days** old to **14 days** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **194**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment will be based on random blocks of size 4

Blinding (investigator's opinion)
Double blinded

Blinding description
In this Study, the parents of participants are unaware of the type of drug used (synbiotic or placebo).The main investigator is blind. One of the personnel is responsible for prescribe and secretly record the type of medication.Residents and other nurses are responsible for collecting data.The data analyst also announces the results in terms of group A, B. The person who evaluate effect of Synbiotic also has no information on the type of prescription drug in every patient.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University Of Medical Sciences

Street address

Siadati Ave, Namjoo Blvd

City

Rasht

Province

Guilan

Postal code

441774349

Approval date

2018-07-26, 1397/05/04

Ethics committee reference number

IR.GUMS.REC.1397.196

Health conditions studied

1

Description of health condition studied

neonatal hyperbilirubinemia and symbiotic effect on its treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bilirubin level

Timepoint

Measurement of Bilirubin in admission day and daily until discharge(8 AM)

Method of measurement

Measurement of serum bilirubin in laboratory by Pars Azmoon kits

Secondary outcomes

1

Description

daily defecation numbers

Timepoint

Daily at 8 AM until discharge

Method of measurement

Question from parents

Intervention groups

1

Description

Intervention group will receive 5 drops of oral Pedilact before breast feeding, once a day, until the day of discharge in addition to routine phototherapy,. Pedilact is a Synbiotic and contains three types of probiotic including Lactobacillus rotieri, Lactobacillus romansus and Bifidobacterium infantis and a prebiotic. It is produced by Iran zist takhmir Company

Category

Treatment - Drugs

2

Description

Control group will receive five drops of diluted formulas once a day as placebo before breastfeeding until the day of discharge in addition to routine phototherapy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar Hospital.

Full name of responsible person

Seyedeh Azadeh Hosseini Nouri

Street address

Siadati Alley, Namjoo St, Gaz Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

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Research Deputy, Siadati Alley. Namjoo Street. Gaz Square

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Seyedeh Azadeh Hosseini Nouri

Position

Assistant Professor of Medical University

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Position

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Person responsible for updating data

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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