Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Study the effect of probiotics in preventing jaundice in newborns.

Protocol summary

Study aim
Investigating the effect of probiotic in preventing jaundice in newborns.
Design
Clinical trials with control group and parallel groups, double blinded and randomization is done by using table of numbers, and 100 infants in each group
Settings and conduct
The study was conducted double blindly and infants who were born in Ghaem Hospital of Mashhad included, taking the drug will Start first day of the birth.
Participants/Inclusion and exclusion criteria
inclusion criteria: Infants with pregnancy age greater than 37 weeks, Birth weight is more than 2500 grams, Parental Satisfaction
Intervention groups
In the Intervention group infants will use a daily yummy capsule (containing 250 mg dry yeast or 1010 Bullardian Saccharomyces organisms for 5 days and in control group placebo capsule will be used in the same way.
Main outcome variables
Amount of bilirubin

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130308012743N2**
Registration date: **2019-10-05, 1398/07/13**
Registration timing: **retrospective**

Last update: **2019-10-05, 1398/07/13**
Update count: **0**
Registration date
2019-10-05, 1398/07/13

Registrant information
Name
Ezat Khodashenas
Name of organization / entity
Mashhad University of Medical Scienses
Country
Iran (Islamic Republic of)
Phone
+98 51 1727 3943
Email address
khodashenase@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-03-21, 1397/01/01
Expected recruitment end date
2019-03-21, 1398/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study the effect of probiotics in preventing jaundice in newborns.

Public title
Study the effect of Probiotics on Neonatal Jaundice Prevention
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Infants with pregnancy age greater than 37 weeks Birth weight is more than 2500 grams Parental Satisfaction
Exclusion criteria:
risk factor for jaundice
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization is performed using random number table through www.randomazation.com and sealed envelope. First, the purpose of the study is explained to the person who meets the requirements, and if the person wishes to sign an informed consent form, they will remove an envelope and place it in the intervention or control group based on the contents of the envelope
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double blind and after full explanation for the newborn's parents and informed consent, they were placed in the intervention and control groups without knowing which group they were in, The person who intervenes does not know which person belongs to which group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی مشهد
Street address
Ghoreishi building, Daneshgah AVE
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Approval date
2018-02-14, 1396/11/25
Ethics committee reference number
IR.MUMS.fm.REC.1396.810

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
Amount of bilirubin
Timepoint
Before the intervention and 3 and 5 days after taking the probiotic capsule
Method of measurement
Skin bilirubinometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Infants will use a daily yummy capsule (containing 250 mg dry yeast or 1010 Bullardian Saccharomyces organisms) for 5 days.
Category
Prevention

2

Description
Control group: Infants in the control group will take one daily capsule of placebo for 5 days.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Ezzat Khodashenase
Street address
Ahmad abad AVE, Ghaem hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
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Phone

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Email

khodashenase@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghoreishi), Daneshgah 16, Daneshgah street

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91778-99191

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Robabeh moosavinesuad chenarani

Position

Non-faculty specialist

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Ahmadabad AVE Ghaem hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ezzat khodashenase

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ezzat Khodashenase

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available