

# 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 Sciences

##### 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.randomization.com](http://www.randomization.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

99199-91766

##### Phone

+98 51 3801 2780

**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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91778-99191

**Phone**

+98 51 3841 2081

**Email**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

99199-91766

**Phone**

+98 51 3801 2780

**Email**

moosavinesuad\_s@yahoo.com

## 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

**Street address**

Ahmadabad AVE Ghaem hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

99199-91766

**Phone**

+98 51 3801 2780

**Email**

khodashenase@mums.ac.ir

## 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

**Street address**

Ahmadabad AVE Ghaem hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

99199-91766

**Phone**

+98 51 3801 2780

**Email**

khodashenase@mums.ac.ir

## **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