Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of the efficiency of Saccharomyces boulardii on neonatal hyperbilirubinemia with placebo on late pereterm and term neonates

Protocol summary

Summary

Objective:The goal of this study was to investigate the efficacy of Saccharomyces boulardii in the treatment of neonatal hyperbilirubinemi in late preterms and term neonates. Design: A prospective, double blinded, randomized, placebo controlled trial. Setting: Single center in Istanbul, Turkey. Patients: Late preterm (34, not completed week – 36, completed gestational weeks) and term (≥ 37 gestational weeks) neonates who need phototherapy for neonatal hyperbilirubinemia Interventions: Neonates were randomized either to receive probiotic (Saccharomyces boulardii 50 mg/kg every 12 hours) or placebo during phototherapy. Main outcome measures: Phototherapy duration, maximum bilirubine level

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012123010279N2**
Registration date: **2013-01-12, 1391/10/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-01-12, 1391/10/23

Registrant information

Name
Ozge Serce Pehlevan
Name of organization / entity
Zeynep Kamil Maternity and Children Education and Training Hospital
Country
Turkey
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08 60 193 612 0900
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Recruitment status

Recruitment complete

Funding source

Drug was insured from Biocodex.

Expected recruitment start date

2012-07-20, 1391/04/30

Expected recruitment end date

2013-08-30, 1392/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficiency of Saccharomyces boulardii on neonatal hyperbilirubinemia with placebo on late pereterm and term neonates

Public title

Saccharomyces boulardii's efficiency on hyperbilirubinemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Late preterm (34, not completed week – 36, completed week) gestational weeks) and term (≥ 37 gestational weeks) neonates 2. Newborns who need phototherapy for neonatal hyperbilirubinemia 3. Newborns who were 0-1 month old. Exclusion criteria: 1. Newborns who have congenital anomalies 2. Newborns who need intense phototherapy 3. Direct coombs positive ABO/Rh incompatability 4. Neonates who have sepsis/pneumonia during phototherapy 5. Neonates with hypothyroidism 6. Neonates who have gastrointestinal obstruction 7. Neonates with asphyxia 8.

Contraindication of peroral feeding

Age

To **1 year** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients were assigned randomly to the study or control group by the principal investigator. Randomization was performed by using sequential numbers generated at the computer center. One nurse who was not involved in the care of the infants prepared Saccharomyces boulardii or distilled water. She gave the prepared material without label to the nurse who was responsible for the infant's care. The first investigator who randomized patients and ordered supplementation to the first nurse gave just only the patients' name to the second investigator for follow-up. Therefore, the only personnel who knew the infants' group assignments were the first investigator and the first nurse, who were not involved in the care of the study infants.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zeynep Kamil Maternity and Children Education and Training Hospital Ethic Commitee

Street address

No:3-4, Dr.Burhanettin Üstünel Sokak, Zeynep Kamil Mahallesi,

City

Istanbul

Postal code

34668

Approval date

2012-07-20, 1391/04/30

Ethics committee reference number

15

Health conditions studied

1

Description of health condition studied

Neonatal hyperbilirubinemia

ICD-10 code

P 59.3

ICD-10 code description

Neonatal jaundice from breast milk inhibitor

Primary outcomes

1

Description

Phototherapy duration

Timepoint

Starts at the same time with the intervention

Method of measurement

Patients' medical records

2

Description

Maximum bilirubinemia level

Timepoint

Starts at the same time with the intervention

Method of measurement

Patients' laboratory records

Secondary outcomes

empty

Intervention groups

1

Description

The study group received Saccharomyces boulardii (Reflor®, Biocodex, France, 50 mg/kg per dose twice daily) during phototherapy.

Category

Treatment - Drugs

2

Description

The control group received placebo (distilled water; 1 cc per dose twice daily) during phototherapy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zeynep Kamil Maternity and Children Education and Training Hospital

Full name of responsible person
Street address
No:3-4, Dr.Burhanettin Üstünel Sokak, Zeynep Kamil Mahallesi,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Health Ministry Drug and Pharmacy General Management
Full name of responsible person
Güven Artıran
Street address
Sokak No:5, Söğütözü Mahallesi
City
Ankara
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Health Ministry Drug and Pharmacy General Management
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty