

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the simultaneous use of Orlistat and phototherapy with standard treatment in the decrease of neonatal jaundice

Protocol summary

Study aim

Comparison of the effect of simultaneous use of orlistat and phototherapy with standard therapy in reducing neonatal jaundice

Design

A clinical trial has been conducted with randomized control and intervention groups. The sample size consists of 64 neonates. Individuals will be randomly assigned to one of the two groups by using the table of random numbers.

Settings and conduct

The present study will be conducted at Qods Hospital of Qazvin. In the intervention group, Orlistat (6mg / kg dose) will be taken orally. The drug will be given to the infant in dissolved in distilled water and phototherapy will be performed according to the standard protocol. Bilirubin levels will be measured in both groups before and after 12 and 24 hours after treatment start. Finally, the data will be entered into SPSS software and statistical tests will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Term neonatal, neonatal weight between 2500- 4000 grams, 2-7 days old neonatal, and total serum bilirubin level 13-25 mg/dl. Exclusion criteria: infants with sepsis, meningitis, congenital anomalies, dehydration, hemolytic disease, Conjugate hyperbilirubinemia.

Intervention groups

Intervention Groups will be included: Group 1 (intervention): Treatment with Orlistat (product of Sanafi Co. at a dose of 6 mg/kg once as an oral consumption suspended in distilled water) and phototherapy (visible light with 490-490 nm wavelength). Group 2 (Control): Treatment with phototherapy.

Main outcome variables

1- Total serum bilirubin 2- Serum conjugated bilirubin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190105042241N1**

Registration date: **2019-03-07, 1397/12/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-07, 1397/12/16**

Update count: **0**

Registration date

2019-03-07, 1397/12/16

Registrant information

Name

gelareh roozbahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3333 4918

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g.roozbahani@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the simultaneous use of Orlistat and phototherapy with standard treatment in the decrease of neonatal jaundice

Public title
Neonatal Jaundice Treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Term neonatal Neonatal weight between 2500- 4000 grams 2-7 days old neonatal Total serum bilirubin level 13-25 mg/dl Direct bilirubin level less than 2 mg/dL or less than 15% from total serum bilirubin
Exclusion criteria:
 Infants with sepsis disease meningitis congenital anomalies dehydration hemolytic disease Conjugate Hyperbilirubinemia

Age
From **2 days** old to **7 days** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
In the present study, individuals will be randomly assigned to one of the two intervention and control groups by using the table of random numbers. There is no precondition for assigning individuals to groups. The randomization unit is Individual. Every participant will have an equal chance of being in each of the groups. Allocation concealment samples are done by the people of the center that they do not have any information about the researcher's aim. The allocation of individuals to groups will be done in an unpredictable random sequence by using the table of random numbers. The path in the random numbers table will be from left to right. Even numbers will be considered for the intervention group and odd numbers for the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Qazvin University of Medical Sciences
Street address
 Dadgostari crossroad, Shahid Bahonar Blvd. Qazvin, Iran
City
 Qazvin
Province
 Qazvin
Postal code
 4595134159
Approval date
 2019-01-07, 1397/10/17
Ethics committee reference number
 IR.QUMS.REC.1397.278

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
 Total serum bilirubin
Timepoint
 Before starting treatment and 12 and 24 hours after starting treatment
Method of measurement
 Standard protocol (Using diazo solutions and photometric method)

2

Description
 Serum conjugated bilirubin
Timepoint
 Before starting treatment and 12 and 24 hours after starting treatment
Method of measurement
 Standard protocol (photometric method)

Secondary outcomes

1

Description
 Length of hospitalization
Timepoint
 End of study

Method of measurement

Based on hours

Intervention groups**1****Description**

Intervention group: Orlistat (a product of Sanafi Co. LTD at a dose of 6 mg/kg once administered as an oral suspension) and phototherapy (visible light with a wavelength of 490-490 nm using the phototherapy machine made by Zardiran Company).

Category

Treatment - Drugs

2**Description**

Control group: Phototherapy (visible light with a wavelength of 490-490 nm using the phototherapy machine made by Zardiran Company)

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Quds Hospital

Full name of responsible person

Gelareh Roozbahani

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Quds Sq., Shahid Beheshti Blvd, Qazvin, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Amir Peymani

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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

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

Murtaza Habibi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences
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Gelareh Roozbahani
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Person responsible for updating data

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is published in Excel format without mentioning patient names.

When the data will become available and for how long

The data will be released from July 2022 for one month.

To whom data/document is available

Medical students, researchers at medical research centers and professors of medical sciences universities

Under which criteria data/document could be used

Comparison of data with other experimental data is allowed. If the article is published, mention should be made of the names of the persons who own the data.

From where data/document is obtainable

The main executor of clinical trial

What processes are involved for a request to access data/document

Submitting a request by the applicant and submitting a letter from the authorized centers.

Comments