Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Survey of Alhagi pseudalhagi effect on blood bilirubin in neonates with hyperbilirubinemia in Shahrekord Hajar hospital

Protocol summary

Summary

The aim of this study was to determine the impact of Alhagi pseudalhagi on neonatal hyperbilirubinemia. This study was a clinical trial performed on term neonates with non hemolytic indirect hyperbilirubinemia. A total of 124 patients were assigned into one of following groups. In the first group, the mother and neonate received Alhagi pseudalhagi 25% cocentration solution, 30 cc and 1cc/kg, respectively, every 8 hours. In the two other groups, either mother or neonate received the solution with the above-mentioned dosage. In the control group, neither mother nor neonate received the solution. The neonates in all groups received phototherapy and the interventions were continued until the serum level of bilirubin decreased to the normal level. The serum level of bilirubin was measured at the baseline and after the intervention and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012042085N6**
Registration date: **2011-01-20, 1389/10/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-01-20, 1389/10/30

Registrant information

Name
Neda Parvin
Name of organization / entity
Shahrekord University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2010-11-22, 1389/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of Alhagi pseudalhagi effect on blood bilirubin in neonates with hyperbilirubinemia in Shahrekord Hajar hospital

Public title

Survey of Alhagi pseudalhagi effect on blood bilirubin in neonates with hyperbilirubinemia in Shahrekord Hajar hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Signing informed consent by parents, total serum bilirubin between 14 and 20 mg/dL, presence of Non hemolytic hyperbilirubinemia, presence of indirect hyperbilirubinemia, hyperbilirubinemia which starts between the third and tenth days after birth, term infant, (Gestational age 42-37 weeks), birth weight 4-5/2 Kg, exclusive breast feeding, Ability of mother to attend the neonate’s bedside, no congenital anomaly, no sepsis, history of asphyxia, or traumatic delivery, no

cephalohematoma, no history of neonatal jaundice, no previous treatment for jaundice, any other treatments or hospitalization, no other treatment with antibiotic or other drugs Exclusion criteria: discharge for any reason before bilirubin less than 12mg/dl, need to other drugs during treatment

Age
From **1 year** old to **1 year** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **124**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahrekord University of Medical Sciences

Street address
Shahrekord University of Medical Sciences

City
Shahrekord

Postal code

Approval date
2009-02-20, 1387/12/02

Ethics committee reference number
2-12-1387

Health conditions studied

1

Description of health condition studied
hyperbilirubinemia

ICD-10 code
P59

ICD-10 code description
Neonatal jaundice from other and unspecified causes

Primary outcomes

1

Description
Serum level of bilirubin

Timepoint
Baseline and then daily during the study

Method of measurement
blood sample

Secondary outcomes

1

Description
hospital stay

Timepoint
During hospital stay

Method of measurement
The number of days that neonate is hospitalized

Intervention groups

1

Description
The mother and neonate received Alhagi pseudalhagi 25% cocentration solution, 30 cc and 1cc/kg, respectively, every 8 hours as well as phototherapy until the serum level of bilirubin decreased to the normal level.

Category
Treatment - Drugs

2

Description
The mother only received Alhagi pseudalhagi 25% cocentration solution, 30 cc every 8 hours as well as phototherapy for the neonates until the serum level of bilirubin decreased to the normal level.

Category
Treatment - Drugs

3

Description
In the control group, neither mother nor neonate received the solution. The neonates only received phototherapy until the serum level of bilirubin decreased to the normal level.

Category
Treatment - Other

4

Description
The neonate only received Alhagi pseudalhagi 25% cocentration solution, 1 cc/kg, every 8 hours as well as phototherapy until the serum level of bilirubin decreased to the normal level.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrekord Hajar Hospital
Full name of responsible person
Neda Parvin
Street address
Shahrekord University of Medical Sciences
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrekord University Of Medical Sciences
Full name of responsible person
Neda Parvin
Street address
Shahrekord University Of Medical Sciences
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrekord University Of Medical Sciences
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

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahrekord University Of Medical Sciences
Full name of responsible person
Neda Parvin
Position
MS
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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