Clinical Trial Protocol
Iranian Registry of Clinical Trials
16 Jan 2021

Effect Of Ursodeoxycholic Acid on indirect Hyperbilirubinemia in Neonates Treated with phototherapy

Protocol summary

Summary
This study was a single blind clinical trial on 220 infants with nonconjugative Hyperbilirubinemia weighing 2500-4000 gr, breastfeeding, 37-41w GA, and age greater than 24h, and Tbili 14-20, Dbili <2mg / dl No incompatibility of ABO, RH, G6PD negative, septicemia, or diseases leading to hyperbilirubinemia: Krigler Najjar, Gilbert, hypothyroidism of preterm infants and diabetic mother who were randomly assigned to receive phototherapy as the control group and receive UDCA + phototherapy They are divided into case groups. To the newborns of the case group, 10 mg / kg / day, BD is given from diluted UDCA capsules and the control group is placed under phototherapy only. On the first day, the levels of TSH, BG, RH, coombs, retic and G6PD, Tbili and Dbili are checked. Information is recorded in forms and phototherapy continues until Tbili = <12 and the time is recorded.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2017071515511N2
Registration date: 2017-08-21, 1396/05/30
Registration timing: retrospective

Last update: Update count: 0
Registration date
2017-08-21, 1396/05/30

Registrant information
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Recruitment status
Recruitment complete
Funding source
Vice-Chancellor for Research of Arak University of Medical Sciences

Expected recruitment start date
2017-02-18, 1395/11/30
Expected recruitment end date
2017-08-21, 1396/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect Of Ursodeoxycholic Acid on indirect Hyperbilirubinemia in Neonates Treated with phototherapy

Public title
Effect Of Ursodeoxycholic Acid on indirect Hyperbilirubinemia in Neonates Treated with phototherapy

Purpose
Treatment

Inclusion/Exclusion criteria
Admission criteria: Neonates with nonconjugate Hyperbilirubinemia weighing 2500-4000 gr; Breastfeeding, 37-41w GA; Age greater than 24h; Tbili = 14-20; Dbili <2mg / dl Exit criteria: Inconsistency of ABO, RH, G6PD negative; Negative septicemia; Diseases leading to Hyperbilirubinemia: Carpenter Najjar, Gilbert, Hyperthyroid hypertrophic hypothyroidism, Preterm and...
diabetic mothers

Age
To 1 day old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: 220

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Placebo Used

Assignment
Parallel

Other design features
Secondary Ids
empty

Ethics committees
1

Ethics committee
Name of ethics committee
Ethics Committee Arak University of Medical Sciences
Street address
Medical School
City
Arak
Postal code
Approval date
2017-02-08, 1395/11/20

Ethics committee reference number
IR.ARAKMU.REC.1395.431

Health conditions studied
1

Description of health condition studied
Hyperbilirubinemia

ICD-10 code
E80

ICD-10 code description
defects of catalase and peroxidase

Primary outcomes
1

Description
Rate Tbili

Timepoint
0, 12, 24 and 48 hours

Method of measurement
Spectrophotometry

Secondary outcomes
1

Description
Rate BG, RH, TSH

Timepoint
first day

Method of measurement
blood test

Intervention groups
1

Description
Case Group: 10 mg / kg / day, BD diluted with water for UDCA capsules

Category
Treatment - Drugs

2

Description
Control Group: Only Phototherapy

Category
Treatment - Drugs

Recruitment centers
1

Recruitment center
Name of recruitment center
Arak Amir Kabir Hospital

Full name of responsible person
Dr. Seyed Mojtaba Hashemi

Street address
Amir Kabir Hospital

City
Arak

Sponsors / Funding sources
1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person
Dr. Mohammad Rafiee

Street address
Medical School

City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Arak 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
empty
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