Effect of Clofibrate in Jaundiced term Newborns

Protocol summary

Summary
The aim of this study was to determine the therapeutic effect of clofibrate in healthy term jaundiced neonates. Healthy, breastfed neonates, uncomplicated delivery between 38th and 41st weeks gestational age were included and babies with congenital anomaly, hemolytic disease (Rh or ABO incompatibility and a positive coombs' test), infection (congenital or acquired), dehydration, G6PD deficiency and conjugated bilirubin>2.0 mg/dl or exceeding 15% of total serum bilirubin were excluded. Thirty neonates (treatment group) were treated with a single oral dose of clofibrate (100 mg/kg) plus phototherapy while another 30 neonates (control group) received only phototherapy. The mean plasma total bilirubin levels were measured at 12, 24 and 48 hours after treatment. Duration of phototherapy also was recorded. Physical examination and liver function tests were controlled for possible side effects.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138706261162N4
Registration date: 2008-10-28, 1387/08/07
Registration timing: retrospective

Recruitment status
Recruitment complete
Funding source
Mashhad University of Medical Sciences

Expected recruitment start date
2002-11-02, 1381/08/11
Expected recruitment end date
2003-07-09, 1382/04/18
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Clofibrate in Jaundiced term Newborns

Public title
Effect of Clofibrate in Jaundiced Term newborns

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: healthy jaundiced, breastfed neonates, delivered between 38th and 41st week of gestational age after an uncomplicated pregnancy and serum bilirubin(TSB) between 17 and 29.9 mg/dl, age less than 28 days exclusion criteria: congenital anomaly, hemolytic disease (Rh or ABO incompatibility and a positive coombs' test), infection (congenital or acquired), dehydration, G6PD deficiency and conjugated bilirubin>2.0 mg/dl or exceeding 15% of total serum bilirubin, age more than 28 days

Age
From 3 years old to 19 years old

Gender
Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-chancellor of Mashhad University of Medical Sciences

Street address

Ghoreshi bulding-Daneshgah Street-Mashhad-Iran

City

Mashhad

Postal code

91379-13131

Approval date

2002-12-02, 1381/09/11

Ethics committee reference number

15169/824

Health conditions studied

1

Description of health condition studied

Jaundice in healthy, term newborn

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum bilirubine

Timepoint

Before intervention-12,24 and 48 after intervention

Method of measurement

Measuring serum bilirubine(diazoo method)

Secondary outcomes

1

Description

Duration of need to phototrapy

Timepoint

daily

Method of measurement

Duration of phototherapy (days)

Intervention groups

1

Description

Phototherapy + clofibrate(100 mg/kg, single dose)

Category

empty

2

Description

Phototherapy

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU Emamreza hospital-Neonatal Research Center

Full name of responsible person

Ashraf Mohammadzadeh

Street address

Neonatal research center- NICU- Emamreza hospital- mashhad-Iran

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Street address

City

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
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

Person responsible for updating data

Contact

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

af@yahoo.com

Web page address
www.mums.ac.ir/nrc

Name of organization / entity
Neonatal Research Center

Full name of responsible person
Ashraf Mohammadzadeh

Position
Neonatologist, Professor

Other areas of specialty/work
NRC-NICU-Emamreza hospital-Mashhad-Iran

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