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

Last update: Update count: 0
Registration date 2008-10-28, 1387/08/07

Registrant information
Name
Ashraf Mohammadzadeh
Name of organization / entity
Neonatal Research Center of Mashhad University of Medical Sciences
Country Iran (Islamic Republic of)
Phone +98 51 1852 1121
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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(diazon method)

**Secondary outcomes**

1

**Description**
- Duration of need to phototherapy

**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 Emaereza hospital-Neonatal Research Center
- **Street address**
  - Neonatal research center- NICU- Emamreza hospital-
- **City**
  - Mashhad

**Sponsors / Funding sources**

1

**Sponsor**
- Name of organization / entity
  - Mashhad University of Medical Sciences
- **Full name of responsible person**
  - Ashraf Mohammadzadeh
- **Street address**
  - 
- **City**
  - Mashhad
- **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
empty
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