Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

To Investigate the Effect of Exchange Transfusion on Prooxidant-Antioxidant Balance (PAB) in Newborns Jaundice

Protocol summary

Summary

Background: Newborns have a limited amount of antioxidant protection. Exchange transfusion may affect Prooxidant-Antioxidant Balance (PAB). The present study is conducted to investigate the effect of the exchange transfusion on PAB in newborns jaundice. Methods: the present study is based on a clinical trial which is conducted in Qaem hospital in Mashhad in 2015-2016 with sampling available on 22 newborns jaundice over 35 weeks with high bilirubin 17 mg / dl who were jaundiced. The instrument of collecting data of the questionnaire of the researcher included maternal blood group and neonatal characteristics (age, sex, weight, gestational age, Apgar score) and laboratory assessment (bilirubin, hematocrit, direct and indirect Coombs, reticulocytes, G6PD, T4, TSH and PAB). The amount of PAB and total serum bilirubin level (STB) of newborns before, after and 6 hours after the exchange transfusion were investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112812197N6**
Registration date: **2016-12-24, 1395/10/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-24, 1395/10/04

Registrant information

Name

Maryam Zakerihamidi

Name of organization / entity

Tonekabon Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 19 1224 5014

Email address

maryamzakerihamidi@yahoo.co.nz

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-07-12, 1393/04/21

Expected recruitment end date

2015-05-08, 1394/02/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To Investigate the Effect of Exchange Transfusion on Prooxidant-Antioxidant Balance (PAB) in Newborns Jaundice

Public title

The Effect of Exchange Transfusion on Prooxidant-Antioxidant Balance

Purpose

Treatment

Inclusion/Exclusion criteria

In this study, the newborns to term and near-term (over 35 weeks) were selected with available sampling. The newborns were enrolled studied after the consent of the parents. Exclusion criteria for studying included severe birth defects; birth asphyxia; respiratory distress; even mild or transient; sepsis; Rh incompatibility and ABO; direct Coombs test positive; maternal diabetes and preeclampsia / eclampsia.

Age
From **2 days** old to **10 days** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **22**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad university of Medical Sciences
Street address
Mashhad- Chahar Rahe Doktora- Mashhad university of Medical Sciences
City
Mashhad
Postal code
Approval date
2014-07-12, 1393/04/21
Ethics committee reference number
930179

Health conditions studied

1

Description of health condition studied
Hyperbilirubinemia
ICD-10 code
P59.0
ICD-10 code description
Neonatal jaundice associated with preterm delivery

Primary outcomes

1

Description
Prooxidant-Antioxidant Balance (PAB)
Timepoint
before, after and 6 hours after the exchange transfusion
Method of measurement
Prooxidant-Antioxidant Balance is considered by TMB in two different reactions

Secondary outcomes

empty

Intervention groups

1

Description
Blood Exchange
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashahd University of Medical Sciences
Full name of responsible person
Research deputy of Mashahd University of Medical Sciences
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Research deputy of Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences, Mashhad, IRAN.
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

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tonekabon Islamic Azad University

Full name of responsible person

Maryam Zakerihamidi

Position

PhD

Other areas of specialty/work

Street address

no 251, Laleh Blind Alley, Golesorkhi St., Chaloos, Iran

City

Chaloos

Postal code

Phone

+98 11 5224 5014

Fax

Email

maryamzakerihamidi@yahoo.co.nz

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maryam Zakerihamidi

Position

PhD

Other areas of specialty/work

Street address

Tonekabon Islamic Azad University, Tonekabon, Iran

City

Tonekabon

Postal code

Phone

+98 11 5427 1105

Fax

Email

maryamzakerihamidi@yahoo.co.nz

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tonekabon Islamic Azad Uniersity

Full name of responsible person

Maryam Zakerihamidi

Position

PhD/Faculty member

Other areas of specialty/work

Street address

no 251, Laleh Blind Alley, Golesorkhi St., Chaloos

City

Chaloos

Postal code

4661734666

Phone

+98 11 5224 5014

Fax

Email

maryamzakerihamidi@yahoo.co.nz

Web page address

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