

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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

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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*

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## Person responsible for general inquiries

### Contact

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*