

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effect of phenobarbital on the need for blood transfusion and neonatal phototherapy in mothers with IUT

Protocol summary

2021-03-17, 1399/12/27

Study aim

Does phenobarbital administration to the mothers undergoing IUT, reduce the need for phototherapy and transfusion in their infants.

Design

This phase 3 clinical trial with a control group, with parallel groups, single-blind, randomized using the Random allocation rule is performed on 38 pregnant women.

Settings and conduct

This randomized clinical trial study, which is performed on 38 pregnant women who are candidates for intrauterine transfusion in Yas Hospital from 2021 to 2022. The sampling method is a convenience method.

Participants/Inclusion and exclusion criteria

Inclusion criteria include all pregnant women with 17 to 35 gestational age and negative RH, Fetus with positive RH and alloimmunization and anemia diagnosis, Perinatal indication for intrauterine transfusion. Criteria for not entering: Existence of any kind of anomaly in the fetus.

Intervention groups

Intervention group: 30 mg phenobarbital is prescribed three times a day, in 10 days till delivery

Main outcome variables

Neonatal jaundice and phototherapy indication

Registrant information

Name

Elham Feizabad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8608 9092

Email address

elhamfeizabad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-19, 1400/01/30

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of phenobarbital on the need for blood transfusion and neonatal phototherapy in mothers with IUT

Public title

Comparison of the effect of phenobarbital on the need for blood transfusion and neonatal phototherapy in mothers with IUT

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women with 17 to 35 gestational age and

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049169N2**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

Registration date

negative RH Fetus with positive RH and alloimmunization and anemia diagnosis Perinatal indication for intra uterine transfusion

Exclusion criteria:

Existence of any kind of anomaly in the fetus

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule: First, 19 letters A and 19 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A or B are determined by a lot.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is performed as single-blind, the pediatric (who assess neonatal jaundice and phototherapy indication), do not know the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, School of Medicine, Tehran Province, Tehran, Pour Sina St" to "Tehran University of Medical Sciences, School of Medicine, Tehran Province, Tehran, Pour Sina St

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2020-12-05, 1399/09/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.850

Health conditions studied

1

Description of health condition studied

Fetal anemia

ICD-10 code

O36.8291

ICD-10 code description

Fetal anemia and thrombocytopenia, unspecified trimester, fetus 1

Primary outcomes

1

Description

Neonatal jaundice

Timepoint

Once

Method of measurement

Pediatric examination and Transcutaneous bilirubinometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the interventional group, 30 mg phenobarbital produced with Marham Daru pharmaceutical co. (two 15 milligram tabs every 8 hours) is prescribed for ten days. According to the time of delivery that is forecasted by the gynecologist, in 10 days till delivery, this drug is prescribed for the pregnant woman.

Category

Treatment - Drugs

2

Description

Control group: In the control group, no additional measures are done and the placebo is not applied.

Category

Treatment - Drugs

Recruitment centers

Recruitment center**Name of recruitment center**

Yas hospital

Full name of responsible person

Fatemeh Rahimi Sharbaf

Street addressYas hospital, Next to the sarv street , North
Nejatollahi street , karim khan ave**City**

tehran

Province

Tehran

Postal code

1597856511

Phone

+98 21 8608 9089

Fax**Email**

rahimish@sina.tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible personVice-Dean of Research of Tehran University of Medical
Sciences, Dr. Sahraiyen**Street address**Vice-Dean of Research, Tehran University of Medical
Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran,
Iran**City**

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1416634793

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Rahimi Sharbaf

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified
participants

When the data will become available and for how long

After manuscript published

To whom data/document is available

No limitations

Under which criteria data/document could be used

The data is only available to the project manager, Dr.
Fatemeh Rahimi Sharbaf, and any analysis must be done
with her opinion.

From where data/document is obtainable

Fatemeh Rahimi Sharbaf

What processes are involved for a request to access data/document

Any request must be made in writing and accompanied
by a proposal with an ethics code under the supervision
of Dr. Fatemeh Rahimi Sharbaf.

Comments