

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Early use of Acetazolamide to prevent progression of Intraventricular hemorrhage in preterm newborns - A Double-Blind Randomized Clinical Trial

#### Protocol summary

##### Study aim

Use of acetazolamide to prevent the development of intraventricular hemorrhage in premature infants

##### Design

This study is a double-blind clinical trial in which 132 premature infants were randomly selected (using a random-number-generator computer program) and the intervention group will be given acetazolamide. The control group will also receive a placebo.

##### Settings and conduct

This is a double-blind clinical trial study in which 132 patients admitted to Shariati and Imam Khomeini hospitals will be considered from the date of receiving the code of ethics in 1400. Blinding includes the Preparation of 66 packs of acetazolamide tablets and 66 packs of placebo tablets, which are the same in terms of appearance, type of packaging, and color. After assigning the tablets to the two groups, We indicate with labels 1 to 132. The researcher delivers the packages to the therapist and the therapist gives the numbers from 1 to 132 to the patients, respectively. The infants are divided into two groups according to the inclusion criteria.

##### Participants/Inclusion and exclusion criteria

All infants admitted to the neonatal intensive care unit in Shariati and Imam Khomeini hospitals in Tehran, under the age of 34 weeks or weighing less than 1700 g in 1400, who according to the brain ultrasound performed have grade 2 or higher intraventricular hemorrhage.

##### Intervention groups

The target group received 1-3 mg per kg acetazolamide PO every three hours until complete cessation of intraventricular hemorrhage. The Control group will receive a placebo with the same appearance as acetazolamide.

##### Main outcome variables

Duration of hospitalization and change in grade of

ventricular hemorrhage and the need for implantation of shunt and seizures and duration of an invasive and non-invasive ventilator and number of deaths and nephrocalcinosis is checked

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210607051507N3**

Registration date: **2021-10-06, 1400/07/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-06, 1400/07/14**

Update count: **0**

##### Registration date

2021-10-06, 1400/07/14

##### Registrant information

##### Name

Ameneh Lamsehchi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6656 1315

##### Email address

lamsehchila@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-06, 1400/06/15

##### Expected recruitment end date

2022-03-06, 1400/12/15

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Early use of Acetazolamide to prevent progression of Intraventricular hemorrhage in preterm newborns - A Double-Blind Randomized Clinical Trial

**Public title**  
To evaluate the effect of acetazolamide in the prevention of intraventricular hemorrhage in preterm newborns

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
All infants admitted to the neonatal intensive care unit at Shariati and Imam Khomeini Hospitals in Tehran under the age of 34 weeks or weighing less than 1700 g in 2020-2021 According to the brain ultrasound performed, they have intraventricular hemorrhage of grade two and above  
**Exclusion criteria:**  
Syndromic cases cases with genetic diseases infants with metabolic and neuromuscular diseases cyanotic heart disease necrotizing enterocolitis gastrointestinal bleeding

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**  
Target sample size: **132**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Using Random number generator computer ( ver.1.1) randomization program, a list of random numbers in the range 1 to 132 will be generated randomly. Random numbers from 1 to 66 will be assigned to the drug and from 67 to 132 to the placebo. Because the order of distribution of these numbers is random, so the assignment of treatment to people who enter the study in order will be done randomly. Finally, this list will be presented to the pharmacist and the order of medicines will be done by the pharmacist in the package, which is the same in terms of shape, appearance, etc. Finally, the therapist will give the pills to the patients using the arrangement of the pills by the drugs.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Because it is a double-blind clinical trial, a randomized

list is provided to the pharmacist to produce a sequence that fits the drug packages so that it is identical in appearance and so on. The packages will then be given to the therapist. Patients will be assigned to treatment according to the order of pills from 1 to 132, which includes 66 packs of acetazolamide tablets and 66 packs of placebo pills, which has been done by the pharmacist according to the random list. After the pharmacist prepares the drugs, he will deliver them to the researcher and the researcher will provide them to the therapist. In this case, the therapist does not know which patient is receiving which treatment after randomization.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

Due to the low dose of acetazolamide used in this study, there will be no side effects and in all studies performed in the years before furosemide and acetazolamide have been used together and in very high doses up to 100 mg per day.

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Tehran, Keshavarz Blvd., Corner of Ghods St., Central Organization of the University, Sixth Floor, Vice Chancellor for Research and Technology, Secretariat of the Ethics Committee in University Biomedical Research - Room 605

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653911

**Approval date**

2021-08-12, 1400/05/21

**Ethics committee reference number**

IR.TUMS.CHMC.REC.1400.093

**Health conditions studied**

**1**

**Description of health condition studied**

Intracranial hemorrhage in preterm newborns

**ICD-10 code**

P52.3

**ICD-10 code description**

Unspecified intraventricular (nontraumatic) hemorrhage

of newborn

## Primary outcomes

### 1

#### **Description**

duration of admission

#### **Timepoint**

Duration of hospitalization of the infant from the start of medication to complete recovery of cerebral hemorrhage and discharge

#### **Method of measurement**

Extract the date of hospitalization and discharge from the file

### 2

#### **Description**

change in the degree of ventricular hemorrhage

#### **Timepoint**

within ten days and one month from the start of acetazolamide

#### **Method of measurement**

Neonatal brain ultrasound and extraction report

### 3

#### **Description**

requirement of shunts

#### **Timepoint**

during of Hospitalization

#### **Method of measurement**

file review

### 4

#### **Description**

seizures

#### **Timepoint**

during hospitalization

#### **Method of measurement**

file review

### 5

#### **Description**

Duration of use of invasive and non-invasive ventilator

#### **Timepoint**

during hospitalization

#### **Method of measurement**

file review

### 6

#### **Description**

Death number of neonates

#### **Timepoint**

during hospitalization

#### **Method of measurement**

file review

## Secondary outcomes

### 1

#### **Description**

nephrocalcinosis

#### **Timepoint**

on one-month

#### **Method of measurement**

ultrasound sonography

### 2

#### **Description**

Evaluation of development

#### **Timepoint**

at a modified four-month age

#### **Method of measurement**

based on ASQ

### 3

#### **Description**

neonatal head circumference (examination of microcephaly or macrocephaly)

#### **Timepoint**

Corrected age of three months

#### **Method of measurement**

meter(cm)

### 4

#### **Description**

hearing change

#### **Timepoint**

at the corrected age of three months

#### **Method of measurement**

ABR audiometer

## Intervention groups

### 1

#### **Description**

Intervention group: They receive acetazolamide at a dose of 1-3 mg per kg per oral every three hours until complete recovery from intraventricular bleeding.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Newborns with the inclusion criteria will receive a placebo with the same appearance as acetazolamide. Due to the low dose and low weight of infants, the main drug is colorless in dilution and distilled water is used as a placebo.

#### **Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shariati Hospital

**Full name of responsible person**

Setareh Sagheb

**Street address**

North Kargar St., Jalal Al-Ahmad Intersection, in front of the Faculty of Economics, Dr. Shariati Research and Treatment Center.

**City**

Tehran

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14117 13135

**Phone**

+98 21 0008 4901

**Email**

shariatihosp@tums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Vice Chancellor for Research and Technology

**Street address**

Keshavarz Boulevard, corner of Ghods, central headquarters of Tehran University of Medical Sciences

**City**

Tehran

**Province**

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**Email**

tumspr@tums.ac.ir

**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**

10

**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**

Persons

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ameneh Lamsehchi

**Position**

Non-faculty specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Setareh Sagheb

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ameneh Lamsehchi

**Position**

Non-faculty specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

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## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available