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
Evalution 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

Province
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

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Tehran

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1417653761

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+98 21 8889 6696

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Setareh Sagheb

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
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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

Street address
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Tehran

Province
Tehran

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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