

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### THE EFFECT OF I/V FUROSEMIDE ON MEAN HOSPITAL STAY AND RATE OF MORTALITY IN TRANSIENT TACHYPNEA OF NEWBORN

#### Protocol summary

##### Study aim

To decrease the patient load in the resource limited setups by decreasing the mean hospital stay of the patients admitted with TTN.

##### Design

Randomized, Concealed, double blinded study

##### Settings and conduct

being conducted in CMH Bahawalpur. it was blinded by the study designer, consultant pediatrician

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Inclusion criteria included all full term and late preterm infants diagnosed with Transient tachypnea of newborn of both sex born via either caesarian section and spontaneous vaginal delivery.  
Exclusion criteria: Exclusion criteria included. Patients of respiratory distress but not under umbrella of Transient tachypnea of newborn. Diagnosis was made on the basis of detailed examination, CXR, blood glucose levels, Complete blood count and C-reactive protein. Patients of the Diseases that were excluded were the cases of Meconium aspiration (Cord and skin stained with meconium , Chest x-rays showing lung opacities and hyperinflation of lungs), Pneumonia (consolidations), Neonatal Respiratory Distress Syndrome(NRDS) (Air bronchograms on CXR), , Neonatal Sepsis(early onset) (positive C reactive protein), Hypoglycemia (BSR less than 54mg/dl respectively), Polycythemia(Hematocrit greater than 60%), Heart Murmur ( via auscultation ) and Tachycardia (heart rate greater than 180/min).

##### Intervention groups

I/V furosemide was given.

##### Main outcome variables

to try to decrease the mean hospital stay of the patients admitted with TTN.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20240601061974N1**

Registration date: **2024-06-08, 1403/03/19**

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

Last update: **2024-06-08, 1403/03/19**

Update count: **0**

#### Registration date

2024-06-08, 1403/03/19

#### Registrant information

##### Name

Sohail Shahzad

##### Name of organization / entity

Cmh bahawalpur

##### Country

Pakistan

##### Phone

+92 62 2501742

##### Email address

cmhbwp31@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2024-06-05, 1403/03/16

#### Expected recruitment end date

2024-07-05, 1403/04/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

THE EFFECT OF I/V FUROSEMIDE ON MEAN HOSPITAL STAY AND RATE OF MORTALITY IN TRANSIENT TACHYPNEA OF NEWBORN

## Public title

role of furosemide in transient tachypnea of newborn

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Inclusion criteria included all full term diagnosed with Transient tachypnea of newborn of both sex born via either caesarian section and spontaneous vaginal delivery. late preterm infants diagnosed with Transient tachypnea of newborn of both sex born via either caesarian section and spontaneous vaginal delivery.

### Exclusion criteria:

Patients of respiratory distress but not under umbrella of Transient tachypnea of newborn. Patients of Meconium aspiration (Cord and skin stained with meconium , Chest x-rays showing lung opacities and hyperinflation of lungs) Patients of Patients of Pneumonia (consolidations) Patients of Neonatal Respiratory Distress Syndrome(NRDS) (Air bronchograms on CXR), Patients of Neonatal Sepsis(early onset) (positive C reactive protein) Patients of Hypoglycemia (BSR less than 54mg/dl respectively) Patients of Polycythemia(Hematocrit greater than 60%) Patients of Heart Murmur ( via auscultation ) Patients of Tachycardia (heart rate greater than 180/min)

## Age

From **1 day** old to **28 days** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

simple randomization was done, it was done on the individual level, sealed envelopes were used to randomize and allocation concealment was carried out.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

it was a double blinded study as the researcher and data analyst were known about the drug being used. drugs were packed in the packed envelopes by the researches mentioning group A and Group B and was administered by the on duty doctors to the patients on the basis of groups mentioned on the envelopes.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethical ommittee of CMH bahawalpur

##### Street address

bahawalpur cant

##### City

Bahawalpur

##### Postal code

63100

#### Approval date

2023-11-01, 1402/08/10

#### Ethics committee reference number

EC-20-2023

## Health conditions studied

### 1

#### Description of health condition studied

Transient tachypnea of newborn

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

I/V feurosemide decreases the mean hospital stay in TTN

#### Timepoint

1-2 days

#### Method of measurement

heart rate using cardia monitor

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:

#### Category

Treatment - Drugs

### 2

#### Description

Control group:

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

CMH bahawalpur

**Full name of responsible person**

Sohail Shahzad

**Street address**

bahawalpur cant

**City**

Bahawalpur

**Postal code**

63100

**Phone**

+92 333 9644384

**Email**

huz.usman99@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

cmh bahawalpur

**Full name of responsible person**

ethical ommittee of CMH bahawalpur

**Street address**

bahawalpur cant

**City**

Bahawalpur

**Postal code**

63100

**Phone**

+92 331 0197878

**Email**

huz.usman99@gmail.com

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

Yes

**Title of funding source**

cmh bahawalpur

**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**

cmh bahawalpur

**Full name of responsible person**

Sohail shahzad

**Position**

consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

bahawalpur cant

**City**

Bahawalpur

**Province**

Punjab

**Postal code**

63100

**Phone**

+92 62 2501742

**Email**

sohailshahzad55@yahoo.com

## Person responsible for scientific inquiries

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

cmh bahawalpur

**Full name of responsible person**

Sohail Shahzad

**Position**

consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

bahawalpur cant

**City**

Bahawalpur

**Province**

Punjab

**Postal code**

63100

**Phone**

+92 62 2501742

**Email**

sohailshahzad55@yahoo.com

## Person responsible for updating data

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

cmh bahawalpur

**Full name of responsible person**

Huzaifa Usman

**Position**

house offier

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Cims boys hostel bwp

**City**

Bahawalpur

**Province**

Punjab

**Postal code**

63100

**Phone**

+92 62 2501742

**Email**

huz.usman99@gmail.com

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

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All the collected data will be shared except their identities

**When the data will become available and for how long**

will be available on demand from the corresponding author

**To whom data/document is available**

all those who require for the study purposes.

**Under which criteria data/document could be used**

for systemic reviews.

**From where data/document is obtainable**

from the corresponding authors

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

by mailing the corresponding authors.

**Comments**