

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

cmhbw31@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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

cmh bahawalpur

Full name of responsible person

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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

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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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

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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