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, doub;e 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

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Email address
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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 envolopes 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
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Sponsors / Funding sources

1

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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
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Other areas of specialty/work
Pediatrics

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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 ollected data will be shared except their identies
When the data will become available and for how long
will be available on demand from the corrosponding 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 corrosponding authors
What processes are involved for a request to access data/document
by mailing the corrosponding authors.
Comments