

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of restrictive fluid management on the outcome of transient tachypnea of the newborn at ahvaz Imam Khomeini hospital

Protocol summary

Summary

In this study which is conducted as a quasi-experimental design, infants older than 34 weeks up to 41 weeks and 6 days of week with a diagnosis of transient tachypnea of the newborn were enrolled. In the control group, in the first day of life 60ml/kg/d, in the second day 80ml/kg/d and from the third day 100 ml/kg/d of 10% dextrose water were administered. In the intervention group, in the first day 40 ml/kg/d, in the second day 60 ml/kg/d and from the third day of life 80 ml/kg/d of 10% dextrose water were prescribed. In cases who were cared under radiant warmer 20 ml per kg is added to the solution volume. The hours of oxygen requirement, the hours of NCPAP requirement and the hours of mechanical ventilation requirement and duration of hospitalization are recorded. inclusion criteria: tachypnoea (RR>60); standing on tachypnea at least for 12 hrs; feature of CXR at least for one of these: prominent pulmonary hilus, increase thickness of lobar fisher due to accumulation of fluid, hilar congestion of both lung, flattening of diaphragm, increase AP diameter of chest exclusion criteria: neonate with congenital anomaly; systemic sepsis; meconium aspiration; RDS; IUGR; fetal distress history; pneumonitis; congenital heart disease; DIC; multi organ failure; hypocalcemia; hypoglycemia; polycythemia; Na>150; Bun>20; K>5; Bill>15; urine out put<1cc/kg/hr

General information

Acronym

TTN

IRCT registration information

IRCT registration number: **IRCT2012111111432N1**

Registration date: **2013-08-23, 1392/06/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-23, 1392/06/01

Registrant information

Name

Anahita Ghaemaghani

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1443 2779

Email address

ghaemaghani.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz, Jundishapur University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of restrictive fluid management on the outcome of transient tachypnea of the newborn at ahvaz Imam Khomeini hospital

Public title

Effect of restrictive fluid management on the outcome of transient tachypnea of the newborn at ahvaz Imam Khomeini hospital

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: neonate with in 34-0/7 to 41-6/7 weeks age with: tachypnoea (RR>60) ;standing on tachypnea at least for 12 hrs; feature of CXR at least for one of these: prominent pulmonary hilus, increase thickness of lobar fisher due to accumulation of fluid, hilar congestion of both lung, flattening of diaphragm, increase AP diameter of chest exclusion criteria: neonate with congenital anomaly; systemic sepsis; meconium aspiration; RDS; IUGR; fetal distress history; pneumonitis; congenital heart disease; DIC; multi organ failure; hypocalcemia; hypoglycemia; polycythemia; Na>150; Bun>20; K>5; Bill>15; urine out put<1cc/kg/hr

Age

To 1 year old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 82

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

AHVAZ ,JUNDISHAPUR UNIVERSITY OF MEDICINE SCIENCES

Street address

ahvaz,golestan Blvd.

City

ahvaz

Postal code

Approval date

2012-07-21, 1391/04/31

Ethics committee reference number

ETH-596

Health conditions studied

1

Description of health condition studied

transient tachypnea of the newborn

ICD-10 code

p22.1

ICD-10 code description

Respiratory distress of newborn

Primary outcomes

1

Description

duration of oxygen requirement

Timepoint

during intervention

Method of measurement

hours

2

Description

duration of CPAP requirement

Timepoint

during intervention

Method of measurement

hours

3

Description

duration of VENTILATOR requirement

Timepoint

during intervention

Method of measurement

hours

4

Description

hospitalized duration

Timepoint

during intervention

Method of measurement

days

Secondary outcomes

1

Description

urine out put

Timepoint

during intervention

Method of measurement

cc/kg/hr

2

Description

serum BUN , CREATININ

Timepoint

during intervention
Method of measurement
serum sampling

3

Description
serum K , Na
Timepoint
during intervention
Method of measurement
serum sampling

4

Description
serum bilirubin
Timepoint
during intervention
Method of measurement
serum sampling

5

Description
specific gravity of urine
Timepoint
during intervention
Method of measurement
with refractometer

6

Description
ABG
Timepoint
during intervention
Method of measurement
artery sampling

Intervention groups

1

Description
In the control group, in the first day of life 60ml/kg/d, in the second day 80ml/kg/d and from the third day 100 ml/kg/d of 10% dextrose water were administered. In cases who were cared under radiant warmer 20 ml per kg is added to the solution volume.
Category
Treatment - Other

2

Description
In the intervention group, in the first day of life 40ml/kg/d, in the second day 60ml/kg/d and from the third day 80 ml/kg/d of 10% dextrose water were administered. In cases who were cared under radiant warmer 20 ml per kg is added to the solution volume.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz, Imam Khomeini hospital
Full name of responsible person
Masud Dehdashtian MD.
Street address
Ahvaz, Azadegan ave.,Imam Khomeini hospital
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz,Jundishapur University of Medical Sciences
Full name of responsible person
Masud Dehdashtian MD.
Street address
Ahvaz,Imam Khomeini hospital,NICU ward
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz,Jundishapur University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz,JundishapurUniversity of medical Sciences
Full name of responsible person
Masud Dehdashtian MD.
Position
Peditric assistant,Imam Khomeini neonatal ward chief
Other areas of specialty/work
Street address
Imam Khomeini hospital, Azadegan avenue, Ahvaz
City
Ahvaz
Postal code
Phone

+98 61 1338 9669

Fax

Email

DEHDASHTIAN@aguns.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz, Jundishapur University of Medical Sciences

Full name of responsible person

Masud Dehdashtian MD.

Position

Pediatric assistant, Imam Khomeini neonatal ward chief

Other areas of specialty/work

Street address

Imam Khomeini, Azadegan Avenue, Ahvaz

City

Ahvaz

Postal code

Phone

+98 61 1338 9669

Fax

Email

DEHDASHTIAN@ajums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz, Jundishapur University of Medical Sciences

Full name of responsible person

Anahita Ghaemaghani

Position

pediatric resident

Other areas of specialty/work

Street address

Imam Khomeini hospital, Azadegan Avenue, Ahvaz

City

Ahvaz

Postal code

Phone

+98 61 1443 2779

Fax

Email

ghaemaghani.a@ajums.ac.ir aa33gg@gmail.com

gh62@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty