

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Conservative with Conventional Management on Hospitalization Period in Newborns with Diagnosis of Transient Tachypnea of Newborns

Protocol summary

Summary

Objective: The purpose of this study is comparison of conservative policy (fluid and electrolyte, Oxygen or NCPAP) with conventional managing (fluid and electrolyte, Oxygen and antibiotics) on duration of oxygen therapy and hospitalization in newborns with transient tachypnea of newborn (TTN). Design: Newborns with diagnosis of transient tachypnea of newborns will be enrolled in this study. Setting and Conduct: Base on the table of random number 130 will be enrolled in this study. The patients will be divided into two groups (conservative and conventional). Newborns will be treated with oxygen or if needed with Nasal Continuous Positive Airway Pressure (NCPAP) and DW10%, 60cc/kg/day on first day of life and daily increment of 20cc/kg till 100cc/kg/day on third days. Sodium chloride 3meq/kg and potassium chloride 2meq/kg will be added to fluid on second days of life. blood culture, chest x-ray and CRP will be taken. Participants (inclusion and exclusion criteria): Inclusion Criteria: gestational age 34-0/7 and 41-6/7; respiratory rate >60/min at first 6 hours of life; persistence of tachypnea for at least 12 hours; appropriate radiographic findings for transient tachypnea of newborns; absence of history of meconium staining; fetal distress; mother's fever; rupture of membrane >18 hours Exclusion Criteria: blood sugar <50mg%; serum calcium <7mg%; hematocrit >60%; hemoglobin <13.5g%; white blood counts <5000/cumm; white blood counts >20000/cumm; absolute neutrophil counts <1750/cumm; immature to mature neutrophil counts ratio >0.2; platelet counts <150000/cumm; positive blood culture; needing to mechanical ventilation; c-reactive proteins >10mg/ml Intervention: In intervention group (conservative) the patients will be treated only with fluid, electrolyte and oxygen or NCPAP. In control group (conventional) beside fluid, electrolyte and oxygen or NCPAP, Ampicillin 150mg/kg/day and

Gentamycin 7.5mg/kg/day will be prescribed. The newborns in conservative groups will be discharged from hospital while subside respiratory distress and tolerate full enteral feeding irrespective of blood culture result. The patients in conventional group will be discharged from hospital after resolution of respiratory distress and full enteral feeding tolerance and prove negative blood culture. All of the newborns will be revisited 2 days after discharge. Outcomes: duration of hospitalization and needing to NCPAP will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102314215N2**

Registration date: **2015-12-21, 1394/09/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-21, 1394/09/30

Registrant information

Name

Masoud Dehdashtian

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Expected recruitment start date

2015-05-10, 1394/02/20

Expected recruitment end date

2015-11-30, 1394/09/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Conservative with Conventional
Management on Hospitalization Period in Newborns with
Diagnosis of Transient Tachypnea of Newborns

Public title

Comparison of Conservative with Conventional
Management in Newborns with Diagnosis of Transient
Tachypnea of Newborns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: gestational age 34- 0/7 and 41- 6/7;
respiratory rate>60/min at first 6 hours of life;
persistence of tachypnea for at least 12 hours;
appropriate radiographic findings for transient tachypnea
of newborns; absence of history of meconium staining;
fetal distress; mother's fever; rupture of membrane>18
hours Exclusion Criteria: blood sugar<50mg%; serum
calcium<7mg%; hematocrit>60%; hemoglobin<13.5g%;
white blood counts<5000/cumm; white blood
counts>20000/cumm; absolute neutrophil
counts<1750/cumm; immature to mature neutrophil
counts ratio>0.2; platelet counts<150000/cumm;
positive blood culture; needing to mechanical ventilation;
c-reactive proteins>10mg/ml

Age

To 1 day old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 130

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Comite of Ahvaz Jundishapur University of
Medical Sciences

Street address

Ahvaz Jundishapur Univerity of Medical Sciences,
Golestan st., Ahvaz, Khozestan Province, IRAN

City

Ahvaz

Postal code

Approval date

2015-05-09, 1394/02/19

Ethics committee reference number

IR.AJUMS.REC.1394.370

Health conditions studied

1

Description of health condition studied

PREVENTIVE

ICD-10 code

P02.7, P03

ICD-10 code description

Fetus and newborn affected by chorioamnionitis:
Amnionitis; Membranitis; Placentalitis, Fetus and newborn
affected by caesarean delivery

Primary outcomes

1

Description

duration of admission

Timepoint

discharge

Method of measurement

hour

Secondary outcomes

1

Description

Duration of NCPAP therapy

Timepoint

Continuous

Method of measurement

Hour

2

Description

oxygen therapy

Timepoint

Continuous

Method of measurement

Hour

Intervention groups**1****Description**

in intervention group DW10% 60ml/kg/d will be prescribed and increases by 20ml/kg/d till 100ml/kg/d. sodium chloride 3meq/kg/d and potassium chloride 2meq/kg/d will be added to fluid from second day of life. oxygen or NCPAP will be used base on severity of respiratory distress.

Category

Prevention

2**Description**

in control group DW10% 60ml/kg/d will be prescribed and increases by 20ml/kg/d till 100ml/kg/d. sodium chloride 3meq/kg/d and potassium chloride 2meq/kg/d will be added to fluid from second day of life. oxygen or NCPAP will be used base on severity of respiratory distress. also ampicillin 150mg/kg/day in three divided doses and gentamycin 7.5mg/kg/day in two divided doses till determination of blood culture will be prescribed.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

masoud dehdashtian

Street address

Azadegan st. Imam Khomeini Hospital, Ahvaz, Khozestan Province, IRAN

City

ahvaz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ghadiri Ataollah

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Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz, Khozestan Province, IRAN

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Ahvaz

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

Yes

Title of funding source

Vice chancellor for research, 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 Jundishapur University of Medical Sciences

Full name of responsible person

Masoud Dehdashtian

Position

Neonatologist

Other areas of specialty/work**Street address**

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Position

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Contact

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Position
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Postal code

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