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-tay 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

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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; Placentitis, 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
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz, Khozestan Province, IRAN
City
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
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Full name of responsible person
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Position
Neonatologist
Other areas of specialty/work
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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