Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the efficacy and safety of needle aspiration and intercostals tube draining, in management of neonatal pneumothorax that receiving assisted ventilation

Protocol summary

Study aim
To compare the efficacy and safety of needle aspiration and chest tube drainage in the management of neonatal pneumothorax

Design
clinical trial with Intervention and control groups and with a parallel design of 116 patients, enrolled in 2019, permuted block randomization, without blinding

Settings and conduct
116 neonates with pneumothorax were selected in 3 hospital(Ali Asghar children's hospital, Akbarabadi hospital and Mahdiyeh hospital). Patients were randomly divided into intevention (needle aspiration method) and control (Chest tube method) groups. After pneumothorax discharge, parameters such as gestational age, birth weight, type of delivery, gender, Apgar score, treatment rate, mortality rate, need for invasive and noninvasive ventilation, blood culture and CRP results, duration of antibiotic use and length of hospitalization, and pneumothorax involvement side were compared in both groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: Parent's Consent, neonates with respiratory support (including endotracheal tube or CPAP or requires more than 40% oxygen) and chest pneumothorax were diagnosed by a physician who were hospitalized in NICU ward , aged lower than 28 day
Exclusion criteria: No parent's Consent, congenital anomaly,lung hypoplasia, peters syndrome, congenital heart disease, pleural effusion, Tension pneumothorax or emergency draining before x-ray.

Intervention groups
In this study, patients were divided 2 group: group 1(intervention): in this group draining of pneumothorax was performed with needle aspiration method group2 (control): in this group draining of pneumothorax was performed with chest tube

Main outcome variables
Successful treatment rate , Complications related to the procedures

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190810044491N1**
Registration date: **2019-09-08, 1398/06/17**
Registration timing: **retrospective**

Last update: **2019-09-08, 1398/06/17**
Update count: **0**

Registration date
2019-09-08, 1398/06/17

Registrant information
Name
Zinat Shakeri
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-02-20, 1397/12/01
Expected recruitment end date
2019-08-23, 1398/06/01
Actual recruitment start date
2019-02-20, 1397/12/01

Actual recruitment end date
2019-08-23, 1398/06/01
Trial completion date
2019-08-23, 1398/06/01

Scientific title
Comparison the efficacy and safety of needle aspiration and intercostals tube draining, in management of neonatal pneumothorax that receiving assisted ventilation

Public title
Comparing Efficacy of Chest Tube drainage and Needle Aspiration for Pneumothorax Treatment in neonates
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Parent's consent to participate in the study Aged lower than 28 day Neonates with respiratory support (including endotracheal tube or CPAP or requires more than 40% oxygen) and chest pneumothorax were diagnosed by a physician who were hospitalized in NICU ward
Exclusion criteria:
No parent's consent Tension pneumothorax or emergency draining before x-ray Lung hypoplasia Congenital heart disease Meconium Aspiration Syndrome (MAS) Congenital Anomalies peters syndrome pleural effusion
Age
From **1 day** old to **28 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **116**
Actual sample size reached: **116**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study was used permuted block randomization. Pateints assigned 2 groups: group A (chest tube method) and group B (Needle Aspiration). Two possible combinations were created for groups AB and BA. Then one of these compounds was randomly selected. This process was repeated several times to obtain the required sample size.
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
Ethics committee of Iran University of Medical Siences
Street address
No. 193, Modares Highway, Vahid Dastgerdy st, Aliasghar Children Hospital
City
Tehran
Province
Tehran
Postal code
1919816766
Approval date
2019-02-19, 1397/11/30
Ethics committee reference number
IR.IUMS.FMD.REC.1398.083

Health conditions studied

1

Description of health condition studied
Pneumothorax, Chest Tube, Needle Aspiration,
ICD-10 code
J93
ICD-10 code description
Pneumothorax

Primary outcomes

1

Description
Successful treatment rate
Timepoint
Before and after draining of pneumothorax
Method of measurement
X-ray and physical examination (neonatologist)

Secondary outcomes

1

Description
Complications related to the procedures (mortality rate, need for invasive and noninvasive ventilation, blood culture and CRP results, duration of antibiotic use and length of hospitalization,)
Timepoint
After draining of pneumothorax
Method of measurement
Physical examination and laboratory test

Intervention groups

1

Description
Intervention group (needle aspiration method): In this group (48 neonates), The thoracentesis was done by aspiration of air using a 10 to 20 cc syringes with a 23 to 25-gauge or 18 to 24 angiocath from the second or third intercostal space and precisely at the top of the rib (to prevent blood vessel damage) in the midclavicular line.

Category
Treatment - Surgery

2

Description
Control group(chest tube method): in this group (68 neonates), Thoracostomy was performed using the chest tube technique by insertion of 10-12F tubes after prep & drep and local anesthesia. A small incision was made at the mid-axillary line of the sixth intercostal space

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Asghar Children's Hospital
Full name of responsible person
Zinat Shakeri
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Modares highway, Vahid Dastgerdy st, Aliasghar Children's Hospital
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2

Recruitment center
Name of recruitment center
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3

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Iran University of Medical Sciences

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
Iran University of Medical Sciences
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Position
Fellow
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
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
Not applicable
When the data will become available and for how long
Not applicable
To whom data/document is available
Not applicable
Under which criteria data/document could be used
Not applicable
From where data/document is obtainable
Not applicable
What processes are involved for a request to access data/document
Not applicable
Comments