

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 intervention (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

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6253

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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 Sciences

Street address

No. 193, Modares Highway, Vahid Dastgerdy st, Aliasghar Children Hospital

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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

Akbar Abadi Hospital

Full name of responsible person

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Molavi st, Bagh Ferdos st, Akbar Abadi hospital

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3

Recruitment center

Name of recruitment center

Mahdijeh Hospital

Full name of responsible person

Zinat shakeri

Street address

Shahid Rajabnia st, Shishegar alley, Fadayian Islam st, Shosh sq, Mahdijeh hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abas motevalian

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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

Full name of responsible person

Zinat Shakery

Position

Fellow

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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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 ProtocolUndecided - 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