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Application of threaded tube in atomisation inhalation

Submission date	Recruitment status	[_] Prospectively registered
08/10/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/10/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/10/2024	Injury, Occupational Diseases, Poisoning	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

In the case of a dry airway, viscous sputum and tracheal intubation easily lead to an increased chance of pulmonary infection in patients. However, at present, the atomization device used to moisten the airway cannot be connected to the mouth end of tracheal intubation, which causes liquid waste during drug atomization inhalation, resulting in insufficient atomization. This study aims to observe the effect of the combined use of threaded tubes and traditional atomisation devices on atomisation inhalation in patients.

Who can participate?

Comatose patients undergoing non-mechanical tracheal ventilation

What does the study involve?

Through convenience sampling, this study enrolled patients undergoing non-mechanical ventilation with endotracheal intubation admitted to the Neurosurgery Department of the Second Hospital of Hebei Medical University between March 2020 and September 2023. The included patients were divided into two groups: the experimental group and the control group. The experimental group was provided with threaded tubes and traditional atomization devices for inhalation, while the control group received only traditional atomization devices.

What are the possible benefits and risks of participating?

Combining threaded tubes and traditional atomisation devices in patients undergoing non-mechanical ventilation with endotracheal intubation may offer potential benefits for airway management and respiratory health.

No risks provided at publication.

Where is the study run from?

The Second Hospital of Hebei Medical University

When is the study starting and how long is it expected to run for?

March 2020 to September 2023

Who is funding the study?
Second Hospital of Hebei Medical University

Who is the main contact?
Dr Liqiao Zhang, liqiao_zhang@126.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Application of threaded tube in atomisation inhalation for patients undergoing non-mechanical ventilation with endotracheal intubation

Study objectives
To observe the effect of the combined use of threaded tubes and traditional atomisation devices on atomisation inhalation in patients.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 02/03/2020, Research Ethics Committee of the Second Hospital of Hebei Medical University (No.215 Heping West Road, Shijiazhuang City, 050000, China; +86 0311 66002811; ydeyjf@126.com), ref: 2020-R073

Study design
Non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Atomisation inhalation for patients undergoing non-mechanical ventilation with endotracheal intubation

Interventions
Comatose patients undergoing non-mechanical tracheal ventilation were included and divided into two groups: the experimental group (n = 56) and the control group (n = 49). The experimental group was provided with a combination of threaded tubes and traditional atomization devices for inhalation, while the control group received only traditional atomization devices.

In the control group, a traditional mask-type atomiser with liquid medicine was employed to align with the end of the endotracheal intubation tube for atomisation inhalation. The experimental group used a threaded tube combined with a traditional atomisation device. The atomizing fluids used included levosalbutamol hydrochloride nebulization solution 0.63g TID, N-acetylcysteine solution for inhalation 0.3g BID, and budesonide suspension for inhalation 2mg BID, with BID administration at 9:00 and 16:00, and TID at 9:00, 17:00, and 1:00. All tubes used had the same inner diameter of 7.5mm. To use the device, the cap at the suction port of the threaded tube was removed, followed by the mask removal. The liquid medicine was then placed into the mask-type atomisation inhalation device, which was connected to the rear end of the threaded tube, while the front end of the threaded tube was connected to the inlet end of the endotracheal intubation tube. Placement was assessed using end-tidal CO_2 monitoring. There was no difference in the time, frequency, and humidifying fluid used for atomisation between

the two groups of patients. Both groups received routine nursing care for endotracheal intubation, and the same suctioning method was used for aspiration of sputum. The nebulizer used in both groups was produced by Ningbo Shengrui Medical Appliance Co., Ltd.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Threaded Tube

Primary outcome measure
The following primary outcome measures were assessed at time points on days 1-5 after humidification:
1. Sputum viscosity is evaluated by clinical doctors based on standardized grading scales 30 minutes after each nebulization session, with assessments carried out twice daily
2. Sputum pH value measured using pH test paper and comparison with the acid-base colorimetric card 30 minutes after each nebulization session, with assessments carried out twice daily

Secondary outcome measures
The following secondary outcome measures were assessed at time points on days 1-5 after humidification:
1. Airway mucosal bleeding measured by observation of airway mucosal bleeding was conducted 30 minutes after each nebulization session, with assessments carried out twice daily
2. Sputum scab formation measured using data recording observations of resistance during the insertion of the conventional suction catheter, small sputum scabs inside the suction catheter during suctioning and/or sputum scabs on the suction catheter during suctioning 4 hours after each nebulization session, with assessments carried out twice daily
3. Respiratory patency measured using a combination of physical examination, including observation and auscultation, the analysis of capnography and ventilator settings to ensure a comprehensive evaluation of airway obstruction and ease of breathing 4 hours after each nebulization session, with evaluations carried out twice daily
4. Pulmonary infection measured by conducting bedside lung ultrasound assessments at a fixed time each day, specifically at 18:00, to provide more continuous and dynamic monitoring of the patient’s pulmonary infection status

Overall study start date
03/03/2020

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Aged 18-88 years old
2. Comatose patients undergoing non-mechanical ventilation with endotracheal intubation
3. Patients whose condition could tolerate atomisation inhalation before an operation
4. Patients whose guardians agreed to participate in this trial and provided written informed consent

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
88 Years

Sex
Both

Target number of participants
105

Total final enrolment
105

Key exclusion criteria
1. Patients with an endotracheal intubation retention time of <5 days
2. Patients who underwent endotracheal intubation and switched to mechanical ventilation on days 1 to 5
3. Patients who underwent mechanical ventilation before switching to non-mechanical ventilation after endotracheal intubation
4. Patients who were intubated and then changed to tracheotomy within 5 days
5. Patients with respiratory failure, heart failure and/or severe liver and kidney diseases
6. Patients with acute respiratory failure or acute renal injury

Date of first enrolment
03/03/2020

Date of final enrolment
01/06/2021

Locations

Countries of recruitment
China

Study participating centre
The Second Hospital of Hebei Medical University
Shijiazhuang
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Sponsor information

Organisation
Second Hospital of Hebei Medical University

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ROR
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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Second Hospital of Hebei Medical University

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

The datasets used and analyzed during the current study are available from the corresponding author, Dr Liqiao Zhang, liqiao_zhang@126.com, on reasonable request.

IPD sharing plan summary

Available on request