ISRCTN24668317 https://doi.org/10.1186/ISRCTN24668317

Quality of life in patients undergoing tracheostomy

Submission date
23/04/2019

Recruitment status
No longer recruiting

Registration date
02/05/2019

Overall study status
Completed

Last Edited
09/01/2023

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tracheostomy is a commonly performed procedure and is intended to provide a long-term surgical airway for patients who are dependent on mechanical ventilation. Due to its invasive and physiologically critical nature, tracheostomy can be associated with morbidity and have significant effects on patients' quality of life. The aim of this study is to assess the quality of life of patients undergoing an elective tracheostomy in Intensive Care Units (ICU), revealing late tracheostomy-related complications and conditions for further improving health.

Who can participate?
Patients who were on mechanical ventilation in the ICU and underwent elective tracheostomy, who had the tracheostomy tube removed more than four months ago

What does the study involve?
Participants' quality of life is assessed using questionnaires. A CT scan and spirometry (breathing) test are performed if needed.

What are the possible benefits and risks of participating?
The benefits of participating are measuring disease impact and assessing quality of life in people undergoing tracheostomy, finding out late tracheostomy-related complications for improving quality of life. A neck CT scan is a convenient and noninvasive way of evaluating problems in the neck. The scan takes little time and is painless. No radiation remains in a patient's body after a CT scan. The x-rays used in standard CT scans have no immediate side effects. There is always a slight chance of cancer from excessive exposure to radiation. However, the benefit of an accurate diagnosis will generally outweigh the risk. The effective radiation dose for this procedure varies. Women should always inform staff if there is any possibility that they are pregnant. CT scanning is, in general, not recommended for pregnant women unless medically necessary because of the potential risk to the baby. Generally, a spirometry procedure is very safe. Some patients report brief shortness of breath or dizziness after the test has been performed, but these will go away after a moment or two. Patients who have recently suffered from a heart attack or any heart-related condition are not ideal candidates for spirometry because the test requires some effort on the patient's part. In very rare cases, spirometry is known to trigger breathing problems in patients.

Where is the study run from?
Yerevan State Medical University (Armenia)

When is the study starting and how long is it expected to run for?
May 2019 to December 2019

Who is funding the study?
Asmida Ltd

Who is the main contact?
Prof. Anna Poghosyan
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Quality of life and late complications in patients undergoing tracheostomy in the ICU

Acronym
QOL after tracheostomy

Study objectives
The study is taking place for assessment of QOL and revealing late complications in patients who underwent tracheostomy. The SRI questionnaire can reliably measure QOL in mechanically ventilated ICU patients who underwent tracheostomy. It may provide clinicians with an accurate assessment of patients' quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/02/2019, YSMU Ethics Board (2 Koryun str. Yerevan, Armenia 0025; Tel: +374 (0)60 621-307, 3-07; Email: ec@ysmu.am), ref: YSMU №7/18-19

Study design
Observational retrospective cohort study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Condition after mechanical ventilation and tracheostomy performed in the ICU

Interventions
Observation of QOL in persons who underwent tracheostomy by filling in the SRI questionnaire. In case of complaints, the cause of the complaints is examined (if needed a tracheal CT scan and spirometry are performed).

Intervention Type
Other

Primary outcome(s)

1. Airway comfort measured using spirometry at baseline from the fourth month after decannulation
2. Dyspnea measured using the Medical Research Council (MRC) scale at baseline from the fourth month after decannulation
3. Wheezing and whistling while breathing measured using the acoustic value at baseline from the fourth month after decannulation
4. Pain measured using numerical rating scale (NRS) requires the patient to rate their pain on a defined scale from 0–10 where 0 is no pain and 10 is the worst pain imaginable, at baseline from the fourth month after decannulation
5. Scar comfort and scar aesthetic measured using Patient and Observer Scar Assessment Scale (POSAS) at baseline from the fourth month after decannulation
6. Neck mobility restriction measured using the range of back bend neck flexion at baseline from the fourth month after decannulation
7. Voice/speech disorders measured using Individual's Self Assessment of how voice problem affects emotions and self-image and ability to communicate effectively in everyday activities and in social and work settings at baseline from the fourth month after decannulation
8. Sleep disturbance measured using Subjective Assessment Measures by FOSQ-10 at baseline from the fourth month after decannulation
9. Swallowing disorders measured using a simple water swallowing test using standard 150 ml of water. Swallowing process assessed under three categories - swallowing speed (ml/s), swallowing volume (ml/swallow) and swallowing duration (s/swallow) at baseline from the fourth month after decannulation
10. Tracheostomy-related operations measured using anamnesis data: yes/no, if yes which kind of operation
11. Feeling of illness measured using standardized Acceptance of Illness Scale (AIS) at baseline from the fourth month after decannulation
12. Quality of life measured using the Severe Respiratory Insufficiency Questionnaire (SRI) at baseline from the fourth month after decannulation

Key secondary outcome(s))
1. Tracheal stenosis measured using CT scan, differentiated as mild, moderate and severe stenosis, at baseline from the fourth month after decannulation
2. Granulation tissue formation measured using clinical assessment at baseline from the fourth month after decannulation
3. Tracheocutaneous fistula measured using clinical assessment at baseline from the fourth month after decannulation
4. Tracheomalacia measured using CT scan at baseline from the fourth month after decannulation

Completion date
15/03/2020

Eligibility

Key inclusion criteria
Patients who underwent tracheostomy in Intensive Care Units (ICU) on mechanical ventilation

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Total final enrolment
156

Key exclusion criteria
1. Does not want to participate in trial
2. Unable to participate due to general health reasons
3. Non tracheostomy related diseases of head and neck

Date of first enrolment
15/05/2019

Date of final enrolment
15/01/2020

Locations

Countries of recruitment
Armenia

Study participating centre
Yerevan State Medical University after Mkhitar Heratsi
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Sponsor information

Organisation
Yerevan State Medical University Heratsi Clinic

ROR
https://ror.org/01vkzj587

Funder(s)

Funder type
Industry

Funder Name
Asmida Ltd

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Anna Poghosyan (anna.yu.poghosyan@gmail.com). Final data regarding QoL assessment results will be available from 01/12/2019. Intermediate data regarding any tools and trial data could be requested any time from 01/06/2019 by email.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/07/2022	18/08/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results	non-peer-reviewed results in preprint	20/08/2020	06/04/2021	No	No
Statistical Analysis Plan	version 0.3		22/08/2022	No	No