ISRCTN16452082 https://doi.org/10.1186/ISRCTN16452082

Factors affecting successful tracheostomy removal: a prospective observational study

Submission date
22/08/2024

Recruitment status
No longer recruiting

Registration date
23/08/2024

Overall study status
Completed

Last Edited
23/08/2024

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A tracheostomy is an opening that is surgically created through the neck into the windpipe to allow air to fill the lungs. This study is looking into the best ways to decide when it's safe to remove a tracheostomy tube. The researchers want to understand which factors can help doctors determine the right time for this important step in a patient’s recovery.

Who can participate?
Patients aged 18 to 80 years who have a tracheostomy and meet certain medical criteria. They should be stable enough to go through some breathing tests and be able to follow simple instructions from their doctors.

What does the study involve?
Participants will undergo a series of breathing tests to measure their lung function. Based on these results, doctors will decide when to try removing the tracheostomy tube. They will also follow up with participants for 60 days to see how they do after the tube is removed.

What are the possible benefits and risks of participating?
Participating may help the researchers find better ways to determine when it's safe to remove a tracheostomy tube, which could benefit future patients. However, as with any medical procedure, there are risks, such as potential breathing difficulties after the tube is removed.

Where is the study run from?
Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
February 2020 to February 2024

Who is funding the study?
Chang Gung Medical Foundation (Taiwan)

Who Is the main contact?
Mrs Mei-Hsiu Chuang, s22006@cgmh.org.tw

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mrs Mei-Hsiu Chuang

Contact details
No.123, Dinghu Road
Gueishan Dist.
Taoyuan
Taiwan
33378
+886 (0)965237785
s22006@cgmh.org.tw

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CMRPG5K0101

Study information

Scientific Title
Predictors of removing tracheostomy in 60 days during the COVID pandemic era: a prospective observational study

Study objectives
Parameters of pulmonary function tests could be used to predict the successful removal of tracheostomy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/02/2020, Chang Gung Medical Foundation Institutional Review Board (199, Tung Hwa North Road, Taipei, 10507, Taiwan; +886 (0)3 3196200; s22006@cgmh.org.tw), ref: 202000095B0

Study design
Single-center diagnostic observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Tracheostomy removal

Interventions
This prospective observational study was conducted to identify optimal indicators for tracheostomy tube removal during the COVID-19 pandemic. The study collected data from patients admitted to Chang Gung Memorial Hospital in Taoyuan between 01/03/2020 and 31/12/2023. The hospital focuses on subacute and chronic care. Patients were evaluated for their suitability for tracheostomy tube removal by pulmonologists or otolaryngologists based on specific criteria, including consciousness level and the ability to cooperate with respiratory tests. Patients with unstable vital signs, those who were pregnant or breastfeeding, or those who could not cooperate with testing were excluded from the study.

Once patients were deemed eligible for decannulation, respiratory therapists conducted tests to collect relevant pulmonary function parameters. Tracheostomy tube removal was performed within 48-96 hours after these tests. The study then observed whether patients could maintain stable respiratory conditions without needing tube reinsertion within 60 days.

Outcome Assessment
The primary outcome of the study was to identify factors that predict successful tracheostomy tube removal within 60 days. Success was defined as the removal of the tracheostomy tube within 3 days without the need for reinsertion within the 60-day observation period. The study's longer observation period compared to other studies aimed to provide a more comprehensive understanding of long-term outcomes. Success rates from previous studies vary, with definitions ranging from decannulation without complications for at least two weeks to not requiring reinsertion for over 72 hours after tube removal.

Covariates
The study collected demographic data including age, gender, smoking habits, and underlying medical conditions such as diabetes, hypertension, heart failure, COVID-19 infection, chronic obstructive pulmonary disease (COPD), pneumonia, and others. Additionally, biochemical profiles and body mass index (BMI) were recorded before the respiratory tests. Pulmonary function-related covariates included the interval between tracheostomy insertion and testing, presence of airway polyps, excessive airway secretions, cough strength, use of a nasogastric tube, and various respiratory parameters such as maximum inspiratory and expiratory pressures, rapid shallow breathing index (RSBI), minute ventilation, tidal volume, respiratory rate, heart rate, oxygen saturation, peak expiratory flow rate (PEFR), and forced vital capacity (FVC). These parameters were measured within 2-4 days before decannulation, with the highest value of three tests being recorded to minimize errors.

Statistical Analysis
The study employed various statistical methods to analyze patient characteristics and differences in respiratory function tests. Categorical variables were analyzed using chi-square or Fisher's exact test, while continuous variables were analyzed using independent t-tests. Logistic regression was used to assess the impact of various covariates on the likelihood of successful

decannulation. Pearson correlation and correlation matrix were utilized to evaluate relationships between covariates. Candidate predictors for successful decannulation within 60 days were identified using C-statistics with a 95% confidence interval. The optimal threshold for these predictors was determined using Youden's J statistic based on the receiver operating characteristic (ROC) curve. The area under the ROC curve (AUROC) was then used to identify the models with the highest predicted probability of successful decannulation. Statistical analyses were performed using IBM SPSS Statistics, with a p-value of less than 0.05 considered statistically significant.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Tracheostomy is removed successfully within 2-4 days after pulmonary test and tracheostomy is not re-inserted for 60 days, measured by observation

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
24/02/2024

Eligibility

Key inclusion criteria
1. Patients available for tracheostomy tube removal
2. Consciousness levels meeting a Glasgow Coma Scale of E4VTM6
3. Able to follow instructions from respiratory therapists for testing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
46

Key exclusion criteria
1. Pregnant or breastfeeding patients
2. Patients with inability to cooperate with testing
3. Patients with unstable vital signs
4. Patients transferred to another hospital

Date of first enrolment
01/03/2020

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Taiwan

Study participating centre
Chang-Gung memorial hospital, Taoyuan branch
No.123, Dinghu Road
Gueishan Dist.
Taoyuan
Taiwan
33378

Sponsor information

Organisation
Chang Gung Medical Foundation

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chang Gung Medical Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analyzed in this study would be available upon adequate request from Mei-Hsiu Chuang (s22006@cgmh.org.tw)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes