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Ultrasonographic evaluation of the submandibular space compliance to predict difficult airway in anaesthesia

Submission date 21/11/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/11/2016	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 09/08/2018	**Condition category** Other	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Oro-tracheal intubation is the placement of a flexible plastic tube through the mouth into the trachea (windpipe) to maintain an open airway. This is required during general anaesthesia, when the patient is connected to a breathing machine (ventilator). Managing the airway is an important skill for anaesthesiologists. It is important for the anaesthesiologist to assess the airway correctly in order to avoid hypoxemic events (low blood oxygen levels) and their consequences. The aim of this study is to find out whether an assessment of the anatomy of the airway can be used to predict the occurrence of airway difficulties in patients undergoing surgery.

Who can participate?
Patients aged over 18 undergoing elective general anaesthesia with oro-tracheal intubation

What does the study involve?
On the day before they undergo surgery, participants undergo an ultrasound scan of the anterior (front) region of the neck to look at the airway structures. Airway difficulties are assessed when the participants are intubated during general anaesthesia.

What are the possible benefits and risks of participating?
The results of this study could help us predict airway difficulties, thereby decreasing the risk of illness or death due to low blood oxygen levels. There are no risks for the participants as ultrasound is non-invasive and does not involve radiation.

Where is the study run from?
The Clinical Emergency County Hospital Cluj (Romania)

When is the study starting and how long is it expected to run for?
October 2016 to June 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18637/20.09.2016

Study information

Scientific Title
Ultrasonographic evaluation of the submandibular space compliance to predict difficult airway in anaesthesia: a prospective diagnostic study

Acronym
HIO-MENTO US

Study objectives
To investigate the ability of ultrasound to evaluate the submandibular space compliance as a predictor for difficult airway in anaesthesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Clinical Emergency County Hospital Cluj, 20/09/2016, ref: 18637

Study design
Prospective diagnostic study

Primary study design
Observational

Secondary study design
Prospective diagnostic study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Management of the difficult airway

Interventions
After the Ethics Committee approval and signing the informed consent forms, adult patients scheduled to undergo general anaesthesia with oro-tracheal intubation are prospectively included. Exclusion criteria are morbid obesity and rapid sequence inductions. Each patient will undergo an ultrasound evaluation of the airway anatomy, focusing on submandibular space compliance. The HMDs (hyo-mandibular distances) are measured in neutral, sniffing, and maximal hyperextended positions, in mid-sagital plane, using a curvilinear ultrasound transducer. The airway ultrasound is performed one day prior to the surgical intervention under general anaesthesia. All intubations are performed in sniffing position, with Macintosh curved laryngoscope blades, with no external laryngeal manipulation. The Cormack grade is registered on first attempt of laryngoscopy. Grades 3 and 4 Cormack-Lehane are considered difficult airway. ROC (receiver operating characteristics) curve analysis is used.

Intervention Type
Other

Primary outcome measure
Submandibular space compliance (the ratio for the hio-mental distance in maximal hyperextended position and sniffing position to the same distance in neutral position), measured by airway ultrasound one day before surgery

Secondary outcome measures
Laryngeal view, assessed using the Cormack grade at induction of anaesthesia during the first laryngoscopy attempt

Overall study start date

01/10/2016

Completion date
30/06/2017

Eligibility

Key inclusion criteria
Patients aged over 18 undergoing elective general anaesthesia with oro-tracheal intubation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Rapid sequence induction
2. External laryngeal manipulation during laryngoscopy
3. Emergency surgery
4. Videolaringoscopy

Date of first enrolment
01/10/2016

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Romania

Study participating centre
The Clinical Emergency County Hospital Cluj
No.3-5, Clinicilor Street
Cluj-Napoca
Romania
400006

Sponsor information

Organisation
The Clinical Emergency County Hospital Cluj

Sponsor details
No 3-5, Clinicilor Street
Cluj-Napoca
Romania
400006

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05j4kzc41

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The abstract will be presented at a conference in 2017 and the full original paper will be published in an anaesthesia journal.

Intention to publish date
30/10/2017

Individual participant data (IPD) sharing plan
All data will be registered in a database and, provided patient confidentiality is protected, can be made available by contacting Cristina Petrisor (petrisor.cristina@umfcluj.ro).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No