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Correct length determination of nasogastric feeding tubes in hospitalized adults in a general hospital

Submission date
31/10/2017

Recruitment status
No longer recruiting

Registration date
03/11/2017

Overall study status
Completed

Last Edited
05/10/2018

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
The placing of nasogastric feeding tubes is a worldwide nursing technique. The correct tip position inside the stomach is essential to administer safe tubefeeding to avoid serious complications that can even cause death. Till now the distance between the nose-ear-xiphoid distance (NEX) still appears to be the gold standard to determine the insertion length of a nasogastric tube. Various studies have already demonstrated that this method is not reliable and suggestions were made for new methods, including the Hanson's formula corrected NEX distance (1979). The aim of this study is to determine whether Hanson's formula corrected NEX distance results in a higher number of correctly placed nasogastric tubes in adults who have a medical need for nasogastric tube placement/tube feeding compared to the NEX distance. The likelihood in obtaining gastric content between both methods after placement of the nasogastric tube will also be studied because this is an important control mechanism to check a correct placement of de tube inside the stomach (and not in the lungs).

Who can participate?
Adults aged 18 and older who have a need for nasogastric tube placement/tube feeding.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have the external length determination of the nasogastric tubes performed using the nose-ear-xiphoid distance. Those in the second group have the external length determination is performed using the Hanson's formula corrected nose-ear-xiphoid distance. In both groups it is attempted to obtain gastric aspirate immediately after placement of the nasogastric tube.

What are the possible benefits and risks of participating?
The findings from this study may help researchers to develop a new easy clinically feasible method for external length determination of nasogastric tubes that contributes to a safer and more efficient placement procedure. Participation in this study does not result in a higher risk of complications due to the intervention compared to other patients who should receive the same intervention during their therapy outside this study.

Where is the study run from?
General Hospital AZ Nikolaas (Belgium)

When is the study starting and how long is it expected to run for?
Septembe 2015 to December 2017

Who is funding the study?
Odisee University College (Belgium)

Who is the main contact?
Mr Tim Torsy
tim.torsy@odisee.be

Study website
https://praktijkgerichtonderzoek.odisee.be/?q=projecten/correcte-lengtebepaling-van-nasogastrische-voedingssondes-bij-meerderjarige-patienten-op

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OCOOR Onderzoek P0139 Nasogastrisch

Study information

Scientific Title

Does the Hanson’s formula corrected nose-ear-xiphoid (NEX) distance results in a higher number of correctly placed nasogastric tubes in hospitalized adults compared to the nose-ear-xiphoid distance (NEX)

Study objectives
The Hanson’s formula corrected nose-ear-xiphoid distance results in a higher amount of correctly placed nasogastric tubes with greater probability in obtaining gastric aspirate compared to the nose-ear-xiphoid distance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Review Committee for Medical Ethics from AZ Nikolaas, 12/11/2015, ref: EC15053

Study design
Blinded prospective randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
This study is conducted in the field of nursing and healthcare in patients with a medical indication for nasogastric tube placement.

Interventions
Participants are randomised to either the control or intervention group by using block randomisation. In the control group external length determination of the nasogastric tubes is performed using the nose-ear-xiphoid distance. In the intervention group external length determination is performed using the Hanson’s formula corrected nose-ear-xiphoid distance. In both groups it is attempted to obtain gastric aspirate immediately after placement of the nasogastric tube.

Intervention Type
Procedure/Surgery

Primary outcome measure

1. The tip position of the nasogastric tube inside the stomach is measured using the technique of X-ray (chest X-ray images) at the moment immediately after inserting/repositioning of the tube
2. The obtainment of gastric aspirate after insertion of the nasogastric tube is measured using a syringe (60 ml) with a conical end and pH indicator strips with a colour 0.5 pH units scale at a time lapse of 1 hour after placement/reposition of the tube

Secondary outcome measures
The association between the study group and the outcome (controlled for age, gender, body length, and cognitive awareness) is measured using a multivariate binary logistic regression analysis at time of data-analysis.

Overall study start date
16/09/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Adult (male/female) >= 18 years
2. Medical indication for nasogastric tube feeding/nasogastric tube placement

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Xiphoid not palpable
2. Documented surgical or anatomically abnormalities of the oesophagus or stomach
3. Not able or unwilling to sign the written informed consent

Date of first enrolment
01/12/2015

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Belgium

Study participating centre
General Hospital AZ Nikolaas
Moerlandstraat 1
Sint-Niklaas
Belgium
9100

Sponsor information

Organisation
Odisee University College

Sponsor details
Research departement
Warmoesberg 26
Brussels
Belgium
1000

Sponsor type
University/education

Website
https://www.odisee.be/en/

ROR
https://ror.org/02c89h825

Funder(s)

Funder type
University/education

Funder Name
Odisee University College

Results and Publications

Publication and dissemination plan
Based on the results of the study, we are planning to write an article for Clinical Nutrition, the official journal of the European Society for Clinical Nutrition and Metabolism (ESPEN). The digital versions of the study protocol, intervention procedures and statistical analysis plan (written in Dutch) are available on request by email (tim.torsy@odisee.be) or by phone (+32495143557).

Intention to publish date
30/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the limitations agreed upon with the central and local Review Committees for Medical Ethics.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018		Yes	No