

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

<b>Submission date</b> 31/10/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/11/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/10/2018	<b>Condition category</b> Respiratory	<input type="checkbox"/> 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 tube feeding 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 the 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?  
September 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**

Mr Tim Torsy

### **Contact details**

Odisee University College  
Campus Waas  
Hospitaalstraat 23  
Sint-Niklaas  
Belgium  
9100  
+32 (0)495 143 557  
tim.torsy@odisee.be

## **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)  $\geq$  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 anatomical 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?
<a href="#">Results article</a>	results	01/12/2018		Yes	No