Gastric Ultrasound Feeding Tube placement confirmation Study. GUT Study

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to determine the accuracy/reliability of ultrasound in determining the correct placement of gastric feeding tube expressed as the sensitivity and specificity for this diagnostic test.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53909

Source
ToetsingOnline

Brief title
GUT study

Condition

- Other condition

Synonym
nvt

Health condition

IC patienten onder sedatie

Research involving
Human

Sponsors and support

Primary sponsor: Intensive care
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Feeding tube, Ultrasound

Outcome measures

Primary outcome

The result of the ultrasound image analysis done by the blinded intensivist in correlation with the golden standard (CXR) will be plotted in a 2x2 table of frequencies. To assess the effectiveness of the test we will calculate its sensitivity and specificity. Sensitivity being the proportion of images correctly categorized as having a "mosaic sign present* by the blinded intensivist out of all images representing a gastric GFT localisation (objectivized by CXR). Specificity being the proportion of images correctly categorized as *mosaic sign absent* out of all images representing a non-gastric GFT localisation.The latter is our primary study parameter to ensure a minimal of false positive results.

The analysis will be done using the statistical program SPSS.

Secondary outcome

Incorrect test results will analysed for a possible correlation to clincal data; patient gender, BMI, PEEP(positive end expiratory pressure), tidal volume, and presence of abdominal gas in left upper quadrant (gastric region) in CXR using logistic regression. These specific clinical parameters have been chosen because they could potentially have influence on the quality of the

ultrasound images produced and therefore on the interpretation of the latter.

Logistic regression calculations will be performed with the use of the

statistical program SPSS.

Study description

Background summary

One of the indications for an X-ray in the ICU is to determine the correct position of the feeding tube in the stomach. Undetected misplacement of the feeding tube in the airway is potentially life-threatening. The use of doppler ultrasound of the stomach could be a good candidate to replace the CXR, but this has not been extensively studied before (1). An ultrasound has several advantages over a CXR. First, it is a bedside diagnostic method that does not require expertise or personnel from outside the ICU and uses equipment already present in a modern ICU. Second, it is safe and has no side effects for the patient or the ultrasound technician. Finally, because the equipment is already present in the intensive care unit, it does not involve any additional cost, whereas a CXR costs about 100 euros (we perform about 2500 CXRs in the ICU every year).

Study objective

to determine the accuracy/reliability of ultrasound in determining the correct placement of gastric feeding tube expressed as the sensitivity and specificity for this diagnostic test.

Study design

A diagnostic study, studying the efficacy of ultrasound in determining the correct placement of the gastric feeding tube in all intensive care patients having or needing one. Patients will get a newly placed gastric feeding tube (GFT) as part of our standard care when admitted to the ICU or a replacement when a new GFT is needed.

When a new GFT is placed or replaced, its position will be determined with the use of ultrasound by a *blinded *ultrasonographer (USG). The USG will repeat the same ultrasonographic measurement with every GFT placement i.e. the presence or absence of a doppler enhancement signal. The presence of the latter indicates the presence of the GFT in the stomach. Every patient will ultimately receive a GFT in the proper position (tested with a CXR), but in order to test the sensitivity and specificity of the ultrasound test we want to perform the

test with the GFT localized at midesophageal level (±30cm), gastric level (±50 cm) and tracheobronchial position (via suction catheter). To test the latter, the trachea of the patient will be injected with 20mL of air through a suction catheter guided through the tracheal tube, while the blinded USG determines the presence or absence of the doppler signal enhancement. The suction catheter in the tracheal tube (similar caliber to the GFT in diameter) is routinely placed as a part of routine care directly after intubation in order to suction secretions in the tracheobronchial system.

We hypothesize that a 20mL air insufflation via a GFT at esophageal level or via a suction catheter in the tracheobronchial system will not show a doppler enhancement signal on ultrasound. This sign will only be objectivized if the GFT is properly positioned in the stomach.
Every patient needing a GFT will be randomized to three different sequences of placement checking.

Intervention

Inject 20 cc of air into the trachea via a suction catheter localized in the endobronchial tube (standard), inject 20 cc of air midesophageal and at stomach level. The order of air injection localization varies between patients and is randomized. The ultrasound technician doing the monitoring is blinded.

Study burden and risks

Burden and risks to the patient are considered minimaal. Patients are already deeply sedated because of the need of intubation so the burden for the gastric tube placement which will happen as part of the standard care is minimaal. The risks of 20cc air insuflation in trachea, oesofagus and stomach are considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

patients that need a gastric feeding tube
patients who need a new gastric feeding tube
patients who have given informed consent

Exclusion criteria

- Does not need a gastric feeding tube and doesn*t have one.
- Laparotomy wound interfering with abdominal ultrasound.
- Patient in prone position.
- Has no informed consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-12-2023
Enrollment:	58
Type:	Actual

Medical products/devices used

Generic name:	Phillips Lumify
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-11-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL79866.058.22