

Comparing two types of tube feeding in patients with severe swallowing difficulties

Submission date 28/12/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/01/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/03/2023	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In patients suffering from severe and chronic dysphagia (swallowing difficulties), a feeding gastrostomy (a special tube placed directly into the stomach) can provide nutritional support. At present, two different types are in clinical use, one type placed by gastroscopy (percutaneous endoscopic gastrostomy [PEG], using a thin, flexible tube called an endoscope) and another type placed using x-ray vision (radiologically inserted gastrostomy [RIG]). The selection of patients to PEG or RIG is often based on rather poorly defined patient factors. The aim of this study is to compare PEG and RIG concerning overall complications, divided into major and minor complications as well as changes in patient-scored health status.

Who can participate?

Patients referred for a feeding gastrostomy and eligible for both methods

What does the study involve?

Participants are randomly allocated to undergo PEG or RIG and are followed up at 10 days in the out-patient department as well as by questionnaire at 30 days after surgery.

What are the possible benefits and risks of participating?

Benefits include an extended and standardised follow up. There are no added risks as both procedures are performed in routine care.

Where is the study run from?

Uppsala University Hospital (Sweden)

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

March 2013 to December 2022

Who is funding the study?

Uppsala University Hospital (Sweden)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

PEG/RIG 2014-281

Study information

Scientific Title

A prospective randomized trial comparing percutaneous endoscopic gastrostomy to radiologically inserted percutaneous gastrostomy

Acronym

PEG-RIG

Study objectives

Percutaneous endoscopic gastrostomy (PEG) is superior to radiologically inserted gastrostomy (RIG) based on overall complications

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/09/2014, the Regional Ethics Committee of Uppsala (Etikprövningsmyndigheten, Box 2110, SE-750 02 Uppsala, Sweden; +46 (0)8 4587070; registrator@etikprovning.se), ref: Dnr: 2014-281

Study design

Randomized controlled 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 to request a participant information sheet

Health condition(s) or problem(s) studied

Severe dysphagia

Interventions

Participants are randomly allocated 1:1 in blocks of 10 with closed envelopes to undergo percutaneous endoscopic gastrostomy (PEG) or radiologically inserted gastrostomy (RIG) and are followed up at 10 days in the out-patient department as well as by questionnaire at 30 days after surgery.

Intervention Type

Procedure/Surgery

Primary outcome measure

Overall complication rate and major and minor complications occurring early (within 10 days) or late (11-30 days) after gastrostomy placement. Major complications are defined as conditions in potential need of reoperation or cardiovascular support, e.g., gastrointestinal perforations, intrabdominal bleeding, aspiration pneumonia or myocardial infarction, while local and self-limiting problems are to be classified as minor.

Secondary outcome measures

Patient-scored health status measured by EQ-5D (EuroQol Research Foundation) at baseline and at 10 and 30 days postoperatively

Overall study start date

14/03/2013

Completion date

31/12/2022

Eligibility**Key inclusion criteria**

Patients referred to the department for a feeding gastrostomy due to severe dysphagia, and eligible for both methods (PEG/RIG)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

180

Key exclusion criteria

Inability to perform an endoscopy due to pharyngo-esophageal obstruction, total or subtotal gastrectomy, other major upper-abdominal surgery, peritoneal carcinosis or ascites

Date of first enrolment

01/10/2014

Date of final enrolment

31/12/2021

Locations**Countries of recruitment**

Sweden

Study participating centre**Uppsala University Hospital**

Dept of Surgical Sciences

Uppsala University

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Sponsor information**Organisation**

Uppsala University Hospital

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Sponsor type

Hospital/treatment centre

Website

<http://www.akademiska.se/>

ROR

<https://ror.org/01apvbh93>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Akademiska Sjukhuset

Alternative Name(s)

Uppsala University Hospital

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Sweden

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2023

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 patient confidentiality

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	28/02/2023	01/03/2023	Yes	No