ISRCTN17642761 https://doi.org/10.1186/ISRCTN17642761

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

Submission date
28/12/2021

Recruitment status
No longer recruiting

Registration date
04/01/2022

Overall study status
Completed

Last Edited
01/03/2023

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Prof. Magnus Sundbom
magnus.sundbom@surgsci.uu.se

Contact information

Type(s)
Scientific

Contact name
Prof Magnus Sundbom

Contact details
Dept of Surgical Sciences
Uppsala University
Uppsala
Sweden
SE-75185
+46 (0)705432989
magnus.sundbom@surgsci.uu.se

Type(s)
Principal investigator

Contact name
Prof Magnus Sundbom

Contact details
Dept of Surgical Sciences
Uppsala University
Uppsala
Sweden
SE-75185
+46 (0)705432989
magnus.sundbom@surgsci.uu.se

Type(s)
Public

Contact name
Prof Magnus Sundbom

Contact details
Dept of Surgical Sciences
Uppsala University
Uppsala
Sweden

SE-75185
+46 (0)705432989
magnus.sundbom@surgsci.uu.se

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
Uppsala
Sweden
SE-75185

Sponsor information

Organisation
Uppsala University Hospital

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

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