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An evaluation of the Medtronic Gatekeeper system in the treatment of subjects with gastro-oesophageal reflux disease (GERD)

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
03/07/2009

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR343

Study information

Scientific Title

Study objectives
The Gatekeeper procedure involves the placement of polyacrylonitrile-based hydrogel prostheses into the oesophageal submucosal space of the lower oesophageal sphincter to prevent reflux.

The Gatekeeper Reflux Repair System offers several advantages to using standard surgical repair or other current endoscopic procedures. These advantages include the ability of the clinician to easily place the prostheses, and placement of the prostheses is reversible.

The purpose of this investigation is to demonstrate the intended use of the Medtronic Gatekeeper Reflux Repair System to provide symptomatic relief in subjects diagnosed with gastro-oesophageal reflux disease (GERD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre, randomised, single blind, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Gastro-oesophageal reflux disease (GERD)

Interventions
The subjects will be randomised to receive the Endoscopy Gatekeeper prostheses or to the endoscopy sham control group with 96 subjects in the treatment arm and 48 subjects in the sham control arm. At 6 months following the initial implant sham procedure, the blind will be broken for all subjects and those randomised to receive the sham procedure will have the opportunity to receive the Gatekeeper procedure. All subjects will complete Symptom

Assessment and Quality of Life questionnaires in the screening procedure and at 6 weeks, 3, 6 12 months and annually until study closure. Upper endoscopy will be performed in the screening procedure and at 3, 6 and 12 months. Oesophageal manometry and 48 hours Bravo pH studies will be performed in the screening procedure and at 6 and 12 months. All subjects must discontinue any PPI therapy at least 7 days prior to study visits. Two weeks after the procedure all subjects will be directed to discontinue their PPI therapy. After discontinuation of PPi's subjects who have persistent symptoms of heartburn or regurgitation may be given anti-reflux medication using the treatment regimen as described in the protocol.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Serious device and procedure related adverse device effects (whether anticipated or unanticipated) at six months post-procedure and the subject's associated symptoms of heartburn at six months post-procedure.

Secondary outcome measures
Improved oesophageal pH defined as the total percent of time that pH is less than 4 at six months post Gatekeeper procedure as compared to baseline.

Overall study start date
13/01/2004

Completion date
12/10/2005

Eligibility

Key inclusion criteria
1. Subjects must be at least 18 years of age
2. Subjects with documented typical symptoms of GERD
3. Female subjects of child bearing potential must have a negative pregnancy test within 1 week before treatment and must agree to use an effective means of birth control during participation in the study
4. Subjects who show symptomatic improvement on PPI and want to discontinue their GERD medication
5. Subjects who have demonstrated a baseline 24 hour ph greater than 4% time with pH less than 4.0
6. Subjects with a baseline GERD-HRQL heartburn score of less than 11 on PPI and greater than 20 off PPI
7. Subjects who have been informed of the nature of the study and have agreed to its provisions and provided ICF, approved by the Institutional Review Board or Medical Ethics Committee of the respective clinical site

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
144

Key exclusion criteria
1. Classified in anaesthesia risk group, American Society of Anaesthesiologists (ASA) class III - IV
2. Extensive barret's oesophagus (greater than 2 cm)
3. Oesophagitis (grades III - IV)
4. Complaints of dysphagia
5. Oesophageal strictures
6. Oesophageal or gastric varices
7. Previous history of gastro-oesophageal surgery, anti-reflux procedures, or gastro-oesophageal or gastric cancer
8. Large hiatal hernia (greater than 3 cm)
9. Ineffective oesophageal motility, defined as amplitudes of less than 30 mmHg greater than 50% of the time
10. Diagnosed with morbid obesity (body mass index [BMI] greater than 35 kg/m^2)
11. Immunocompromised subjects (subjects diagnosed with human immunodeficiency virus (HIV), on chronic steroid use or other immunosuppressants, such as Immuran)
12. History of bleeding diathesis or coagulopathy or who will refuse blood transfusions
13. Inability to discontinue anticoagulation therapy
14. Suffered a stroke or transient ischemic neurological attack (TIA) within the past 6 months
15. Experienced a haematologically significant gastrointestinal bleed within the past 6 months
16. Has other medical illness that may cause the subject to be non-compliant with or unable to meet the requirements of the protocol or is associated with limited life expectancy
17. Simultaneously participating in another device or drug study, or who has participated in any clinical trial involving an experimental device within 6 months or experimental drug within 30 days of study entry
18. Unable or unwilling to cooperate with study procedures

Date of first enrolment
13/01/2004

Date of final enrolment
12/10/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Department of Endoscopy
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Medtronic Gastroenterology/Urology (MGU) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration