# An evaluation of the Medtronic Gatekeeper system in the treatment of subjects with Gastroesophageal reflux disease (GERD).

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N/A

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON29549

**Bron**
NTR

**Verkorte titel**
N/A

**Aandoening**

GERD

### Ondersteuning

**Primaire sponsor:** Medtronic Gastroenterology/Urology
4000 Lexington Avenue North
Shreview, MN 55126-3755

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Serious device- and procedure related adverse device effects (whether anicipated or unanticipated) at 6 months post procedure and the subject's associated symptoms of heartburn at 6 months post procedure.

# Toelichting onderzoek

**Achtergrond van het onderzoek**

The Gatekeeper procedure involves the placement of polyacrylonitrile-based hydrogel prostheses into the esophageal submucosal space of the lower esophageal 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 GERD.

It is a prospective, randomized, sham-controlled, single-blinded, multicenter study with an approximate total of 144 implanted male and female subjects with gastroesophageal reflux disease showing symptomatic improvement on proton pump inhibitors who satisfy all entry criteria.
These subjects will be randomized to receive the Gatekeeper prostheses or to the sham control group with 96 subjects in the treatment arm and 48 subjects in the sham control arm.

All subjects in the sham control group will be given the option of crossing over to the active treatment group after a minimum period of 6 months has transpired following the initial sham procedure.

All subjects will be followed closely for up to 18 months ( depending on their randomization group), and then once a year after that until the study closes.

Primary endpoints:

Serious device- and procedure-related adverse device effects (whether anticipated or unanticipated), at 6 months post-procedure and the subjects’ associated symptoms of heartburn at 6-months post-Gatekeeper procedure.

Secondary endpoints:

Improved esophageal pH defined as the total percent of time that pH is less than 4 at 6 months post-Gatekeeper procedure as compared to baseline.

### Doel van het onderzoek

N/A

### Onderzoeksopzet

N/A

### Onderzoeksproduct en/of interventie

The subjects will be randomized 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 randomized to receive the sham procedure will have the opportunity to receive the Gatekeeperprocdure. All subjects will complete Symptom Assesment and Quality of Life questionnaires in the screening procedure and at 6 weeks, 3, 6 12 months and annualy until study closure. Upper endoscopy will be performed in the screening procedure and at 3, 6 and 12 months. Esophageal 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. 2 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.

## Contactpersonen

### Publiek

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 improvemnet on PPI and want to discontinue their GERD medication;

5. Subjects who have demonstrated a baseline 24 hour ph> 4% time with pH< 4.0;

6. Subjects with a baseline GERD-HRQL heartburn score of < 11 on PPI and > 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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Cassified in anesthesia risk group, ASA Class III-IV;

2. Extensive barret's esophagus (> 2cm);

3. Esophagitis (Grades III-IV);

4. Complaints of dysphagia;

5. Esophageal strictures;

6. Esophageal or gastric varices;

7. Previous history of gastroesophgeal surgery, anti-reflux procedures, or gastroesophageal or gastric cancer;

8. Large hiatal hernia (> 3cm);

9. Ineffective esophageal motility, defined as amplitudes of < 30 mmHg> 50% of the time;

10. Diagnosed with morbid obesity (BMI >35);

11. Immunocompromised subjects (subjects diagnosed with 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 hematologically 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 associatedwith limited life expectancy;

17. Simultaneously participating in another device or drug study, or who has participated in any clincal trila 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.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Placebo |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 13-01-2004 |
| Aantal proefpersonen: | 144 |
| Type: | Werkelijke startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 12-09-2005 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL305 |

| Register | ID |
| --- | --- |
| NTR-old | NTR343 |
| Ander register | : N/A |
| ISRCTN | ISRCTN41367345 |

# Resultaten

**Samenvatting resultaten**
N/A