Benesco TM for reflux symptoms

Published: 05-03-2021
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We hypothesize that benesco TM reduces symptoms, esophageal acid sensitivity and permeability in patients with reflux symptoms

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON27122

Source
NTR

Brief title
TBA

Condition

- Gastrointestinal motility and defaecation conditions

Health condition

Reflux

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: Thelial BV

Intervention

- Food (substances)

Explanation

Benesco

Outcome measures

Primary outcome

The main objective of the study is to investigate if benescoTM reduces symptoms (study part A), esophageal acid sensitivity and permeability (study part B) in patients with reflux symptoms.

Secondary outcome

Reduction in symptom frequency and symptom severity (using a symptom diary). (A) To evaluate whether benescoTM results in improvement of the esophageal barrier function.(B)

Study description

Background summary

Rationale: Gastroesophageal reflux disease (GERD) is one of the most common gastro-intestinal disorders with an estimated prevalence of 7%-33% worldwide. Although proton pump inhibitor (PPI) therapy forms the mainstay of GERD management, approximately one-third of the patients experience persistent symptoms despite daily PPI use. Moreover, a subset of patients does not want to use PPI and seeks for alternative therapies because of assumed side effects such as dementia, osteoporosis and pneumonia. Given the high prevalence of GERD, reflux symptoms represent a significant clinical problem and press a high burden on current health care. Esophageal mucosal barrier function, as the underlying cause of esophageal hypersensitivity, is considered a potential therapeutic target in reflux disease. benescoTM is an over-the-counter nutritional supplement containing quercetin, a naturally-occurring flavonoid that has a long history of consumption as part of the normal human diet. Previous studies demonstrated that oral quercetin supports esophageal barrier function and acid resistance. However to date, the clinical efficacy on reflux symptoms and the effect on acid sensitivity in humans has not been studied yet. If we are able to demonstrate the clinical effect of benescoTM for reduction of reflux symptoms and confirm its role in supporting esophageal barrier function and acid perception in humans, it will support the use of benescoTM as a valuable natural alternative to PPI-treatment. Objective: to assess the effect of benescoTM on reflux symptoms (part A) and secondly on esophageal sensitivity to acid and mucosal barrier function (part B). Study design: A single centre, double-blind placebo-controlled randomized trial Study population: 108 patients with reflux symptoms (100 in part A; 8 in part B) Intervention: Part A: during the study period of 6 weeks, patients

will receive 3 times daily 200 mg of benescoTM or a placebo. Patients will fill out symptom questionnaires at baseline and every week for the total duration of the study (6 weeks) Moreover, patients will report a daily symptom diary. Eight reflux patients are asked to participate in the mechanistic intervention study (study part B). These subjects will undergo additional testing at baseline and after 6 weeks of benescoTM by means of upper endoscopy with biopsy sampling, electrical tissue impedance spectroscopy and an acid perfusion test. Main study parameters/endpoints: the primary outcome is treatment success, defined as a reduction in symptoms of 50%. Secondary outcomes include reduction in symptom frequency and symptom severity (using a symptom diary). Nature and extent of the burden and risks associated with participation, benefit and group relatedness: For the treatment period of six weeks, subjects will fill out short symptom diaries and weekly symptom questionnaires (on six separate occasions). There will be one study visit, which can be either a physical visit to the hospital or a video conference call. benescoTM is an over-the-counter nutritional supplement containing quercetin. Numerous clinical studies have proven good safety of quercetin and no compound-related adverse effects or evidence for toxicity have been found. The subgroup of subjects that will participate in the part B study, will undergo two upper endoscopies with biopsy sampling and two esophageal acid perfusion tests. Both endoscopy and acid perfusion test cause mild discomfort. Sedation can be provided on demand. Risk of perforation or bleeding of biopsy taking is smaller than 1/10000 endoscopies. Participants will be compensated financially for participation in the study and the findings could help treat future patients with similar complaints.

Study objective

We hypothesize that benesco TM reduces symptoms, esophageal acid sensitivity and permeability in patients with reflux symptoms

Study design

6 weeks

Intervention

Part A: during the study period of 6 weeks, patients will receive 3 times daily 200 mg of benescoTM or a placebo. Patients will fill out symptom questionnaires at baseline and every week for the total duration of the study (6 weeks) Moreover, patients will report a daily symptom diary. Eight reflux patients are asked to participate in the mechanistic intervention study (study part B). These subjects will undergo additional testing at baseline and after 6 weeks of benescoTM by means of upper endoscopy with biopsy sampling, electrical tissue impedance spectroscopy and an acid perfusion test.

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Adults (18-64 years)
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: - Written informed consent. - Both male and female patients will be included. - Age above 18 years. - Symptoms of heartburn and/or acid regurgitation at least 3 times a week - A total reflux symptom score ≥8 (measured through the GerdQ questionnaire score).

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: - Use of any medication with an effect on gastrointestinal motility, secretion or sensitivity that cannot be stopped for the duration of the study except antacids (e.g. proton pump inhibitors, H2-blockers, antidepressants, prokinetics). Medication must be stopped at least two weeks upon inclusion. - Less than 50% response to PPI (if previously used) - Known Barrett’s esophagus - History of gastric or esophageal surgery - Known allergy to one of the

ingredients of Benesco - Severe and clinically unstable concomitant disease (e.g. liver, cardiovascular or lung disease, neurological or psychiatric disorders, cancer or AIDS and other endocrine disorders) - Pregnant, lactating or fertile women (without contraception)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2021
Enrollment:	108
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	17-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

ID: 54012
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9324
CCMO	NL75630.018.20
OMON	NL-OMON54012

Study results

Results posted: 31-01-2024

Actual enrolment: 108

Summary results
One hundred participants were randomized. Treatment success was seen in 18 (39%) of 46 participants in the intervention group versus 21 (47%) of 45 in the placebo group (p = 0.468). In the intervention group 10 (1–21) reflux-free days were reported compared to 10 (2–25) in the placebo group (p = 0.673). In addition, 38 (34–41) versus 39 (35–42) reflux-free nights were reported (p = 0.409).

First publication
10-07-2023

URL result
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