The effect of on demand versus continuous use of proton pump inhibitors on reflux symptoms, quality of life and self-rated health in patients with gastro-oesophageal reflux disease

Published: 21-07-2014
Last updated: 21-04-2024

Objective 1: To investigate the difference in prescribing proton pump inhibitors continuously rather than on demand in patient reported reflux symptoms, quality of life and self-rated health. Objective 2: To investigate whether the use of electronic...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal disorders
Study type	Interventional

Summary

ID

NL-OMON41804

Source
ToetsingOnline

Brief title
Effect of on demand versus continuous use of omeprazole on reflux symptoms

Condition

- Gastrointestinal disorders

Synonym
gastro-oesofageal reflux disease; reflux

Research involving
Human

Sponsors and support

Primary sponsor: Karolinska Institutet
Source(s) of monetary or material Support: the European Union□s Seventh Framework Programme for research;technological development and demonstration under grant agreement no 247787 [TRANSFoRm]

Intervention

Keyword: gastro-oesophageal reflux disease, proton pump inhibitor, quality of life, self-rated health

Outcome measures

Primary outcome

Difference in reflux disease questionnaire score and self-rated health

(Objective 1) and per cent recruited patients (Objective 2) between trial

arms.

Secondary outcome

Self-rated health (Objective 1), Quality of life as assessed by SF-12

(Objective 1), Completion rate (Objective 2), User acceptance and usability

(Objective 2)

Study description

Background summary

Gastro-oesophageal reflux disease (GORD) includes a spectrum of disorders mainly caused by the retrograde flow of acid gastric contents form the stomach into the oesophagus, causing symptoms and/or oesophageal mucosal damage. Heartburn and acid regurgitation (a bitter burning taste at the back of the mouth) are the most typical symptoms of GORD. GORD is a chronic disease (prevalence 10-20 % in Europe) with a negative effect on quality of life (QoL). GORD is mainly treated in primary care with a proton pump inhibitor (PPI) eg 20 mg omeprazole once or twice daily or on demand. The data on which treatment regime is superior is conflicting and this lack of knowledge is likely to be related to the difficulties of performing large randomised controlled trials in

primary care. In addition, patient reported outcomes such as symptom frequency and severity, QoL and self-rated health are important measures but are rarely used in primary care today. The goal of the TRANSFoRm project is to develop tools to facilitate the conduction of RCTs in primary care, including the collection of both care reported outcomes and patient reported outcomes.

Study objective

Objective 1: To investigate the difference in prescribing proton pump inhibitors continuously rather than on demand in patient reported reflux symptoms, quality of life and self-rated health.

Objective 2: To investigate whether the use of electronic tools for data collection results in a higher recruitment rate than standard paper-based procedures.

Study design

Randomized controlled trial (Objective 1) within a clustered randomized controlled trial (Objective 2).

Intervention

Patients will be randomized to either continuous use of PPI (20 mg omeprazole daily) or on demand (20 mg Omeprazol on demand, maximum daily dose is 40 mg) (Objective 1). Primary health care centres enrolling patients will be randomized to perform the study with the use of electronic tools for data collection or the use of standard trial methods for data collection (Objective 2).

Study burden and risks

The patient will be randomized to one of two standard treatments of GORD. Thus, the intervention per se cannot be considered a burden for the patient. The patient will complete questionnaires for patient reported outcome measures at the start of the study and after 8 weeks, which is estimated will take approximately 20 minutes to complete. Knowledge of which of these standard treatments gives the most symptom relief will be used to further clarify treatment regiments for GORD and thus be used to improve quality of care for patients with GORD in primary care across Europe. Thus, the benefits of the study are deemed to exceed the burden and risks for participating patients.

Contacts

Public
Karolinska Institutet

Alfred Nobels allé 12
Huddinge SE-141 83
SE
Scientific
Karolinska Institutet

Alfred Nobels allé 12
Huddinge SE-141 83
SE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age 18-65 years
* Predominant GORD cases with heartburn and/or acid regurgitation that need PPI treatment
* PPI responsive
* Ability to complete questionnaires

Exclusion criteria

* Known Barrett*s oesophagus
* Known severe oesophagitis (LA C or above)
* Continuous use of NSAID/aspirin
* Prophylactic PPI use to reduce the risk of ulcers in persons being treated with NSAIDs

* PPI treatment to heal an ulcer induced by NSAID treatment in the last 6 months
* PPI treatment for H. pylori eradication in the last 6 months
* Severe disorders other than GORD with a negative impact on quality of life
* Signs of upper gastrointestinal bleeding
* Alarm symptoms: unintentional weight loss/vomiting/difficulties swallowing
* Pregnancy

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2015
Enrollment:	140
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Losec
Generic name:	Omeprazole
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	21-07-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-03-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2014-001314-25-NL
CCMO	NL49118.029.14