

On demand versus continuous use of omeprazole on reflux symptoms (3)

Submission date 04/03/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 05/03/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/10/2020	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Gastro-oesophageal reflux disease (GORD) refers to a range of disorders mainly caused by the backward flow of acid from the stomach into the oesophagus (gullet). 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) that has a detrimental effect on a person's quality of life (QoL). It is mainly treated in primary care (for example, the GP surgery) with a proton pump inhibitor (PPI) once or twice a day, or on demand. There is conflicting data on which of these two treatment regimens is better and this lack of knowledge is likely to be related to the difficulties of performing large studies in primary care. In addition, patient reported outcomes such as symptom frequency and severity, QoL and self-rated health are important but are rarely used in primary care today. This study has been developed to answer the question "what gives most symptom relief and improvement in quality of life in patients with GORD, on demand or continuous use of proton pump inhibitors?"

Who can participate?

Adults aged between 18-65 years, diagnosed with GORD that responds to PPI treatment.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 are treated with regular use of proton pump inhibitors. Those in group 2 are treated with on demand use of proton pump inhibitors. In this pilot study, the TRANSFoRm* tool is tested in 5 countries with 8 primary care practices each, including 20 patients per practice. The progress of each patient is followed for 8 weeks.

* TRANSFoRm is a project to develop tools to help in the running of clinical trials in primary care, including the collection of both care reported outcomes and patient reported outcomes. It also aims to develop a suite of software tools and underlying infrastructure to support primary and epidemiological research

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?
Karolinska Institute (Sweden)

When is the study starting and how long is it expected to run for?
March 2015 to May 2015

Who is funding the study?
The European Commission (Belgium)

Who is the main contact?
Ms Ellen Wright

Contact information

Type(s)
Public

Contact name
Ms Ellen Wright

Contact details
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Additional identifiers

Clinical Trials Information System (CTIS)
2014-001314-25

Protocol serial number
18049

Study information

Scientific Title
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

Study objectives
The aim of this study is to determine what gives most symptom relief and improvement in quality of life in patients with gastro-oesophageal reflux disease (GORD): on demand or continuous use of proton pump inhibitors

Ethics approval required
Old ethics approval format

Ethics approval(s)

14/WM/1196

Primary study design

Interventional

Study design

Randomised; Interventional and Observational; Design type: Treatment, Qualitative

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Primary Care; Subtopic: Primary care; Disease: All Diseases

Interventions

Drug treatment

Regular versus on demand dosing of omeprazole for control control of reflux symptoms.

Intervention Type

Drug

Primary outcome(s)

Reflux symptoms; Timepoint(s): At recruitment and at 8 weeks follow up

Key secondary outcome(s)

N/A

Completion date

31/05/2015

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Total final enrolment

488

Key exclusion criteria

1. Known Barrett's oesophagus
2. Known severe oesophagitis (LA C or above)
3. Continuous use of NSAID/aspirin
4. Prophylactic PPI use to reduce the risk of ulcers in persons being treated with NSAIDs
5. PPI treatment to heal an ulcer induced by NSAID treatment in the last 6 months
6. PPI treatment for H. pylori eradication in the last 6 months
7. Severe disorders other than GORD with a negative impact on quality of life
8. Signs of upper gastrointestinal bleeding
9. Alarm symptoms: unintentional weight loss/vomiting/difficulties swallowing
10. Pregnancy

Date of first enrolment

14/03/2015

Date of final enrolment

31/05/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

King's College Hospital

Division of Primary Care and Public Health Sciences

Capital House

42 Weston Street

London

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SE1 3QD

Sponsor information

Organisation

Karolinska Institute

ROR

<https://ror.org/056d84691>

Funder(s)

Funder type

Government

Funder Name

European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results presented at the American Gastroenterological association (AGA) conference	01/05/2019	06/10/2020	No	No
HRA research summary			28/06/2023	No	No