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

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

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

EudraCT/CTIS number
2014-001314-25

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

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

Secondary outcome measures
N/A

Overall study start date
14/03/2015

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 700; UK Sample Size: 140

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

England

United Kingdom

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

Sponsor details
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Stockholm
Sweden
171 77
-
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Sponsor type
University/education

Website
http://ki.se

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, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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

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