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Drug treatment of Laryngopharyngeal Reflux (LPR)

Submission date
07/09/2011

Recruitment status
Stopped

Registration date
06/10/2011

Overall study status
Stopped

Last Edited
10/09/2013

Condition category
Digestive System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Laryngopharyngeal reflux, the backflow of acid into your oesophagus and into your throat and voice box, has been cited as a cause for a wide range of complaints. These include hoarsenss, a sensation of a lump in the throat, sore throats, chronic cough, and chronic throat clearing. There are no tests that can be done that reliably, in all patients, diagnose the condition and so medications are often given on the basis of the clinical history and physical examination findings. Patients are often given prolonged courses of proton pump inhibitors which suppress stomach acid (gastric acid) production, in an effort to improve symptoms. However, trials with proton pump inhibitors have shown little benefit over inactive medicine (placebo), but have often used small numbers of patients and have had shortcomings in the way the study was designed . A promising trial has shown the benefit of a liquid preparation, called an alginate, which binds to the damaging components of the stomach contents and helps to reduce the extent of backflow (reflux) of material into the gullet (oesophagus).

Who can participate?
We will enrol patients with laryngopharyngeal reflux who have been referred from their GP to hospital for an ENT specialist (otolaryngological) opinion.

What does the study involve?
The consenting patients will undergo a medical consultation including physical examination and will complete a questionnaire. A subgoup will undergo physiological testing and a surgical procedure to remove tissue for examination (small tissue biopsies) taken from the back of the throat under local anaesthetic in the clinic. They will then take a tablet medication once a day (either the genuine drug or a placebo) and a liquid preparation (either the medication or a placebo) four times per day. The tests will then be repeated up to 6 months after the initial consultation. Patients will be randomly allocated and will not know whether they are receiving the genuine drug or the placebo.

What are the possible benefits and risks of participating?
There is no therapeutic benefit from the placebo. There are no known significant side effects of 6 month treatment with these medications and they are the current treatment of choice prior to this study.

Where is the study run from?
The study will be run from Southampton Clinical Trials Unit and will include about 10 centres across the UK plus centres in Europe.

When is the study starting and how long is it expected to run for?
Recruitment to the trial will likely commence in January 2013 and is likely to continue until June 2015.
Updated 10/09/2013: this trial has been stopped due to lack of staff/facilities/resources

Who is funding the study?
We are in the process of applying for funding from the National Institute for Health Research (UK).

Who is the main contact?
Mr Steven Frampton
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Contact information

Type(s)
Scientific

Contact name
Dr Emma King

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A randomised controlled trial of the efficacy of a Proton Pump Inhibitor (PPI) and / or alginate in the treatment of Laryngopharyngeal Reflux (LPR) in adult patients in secondary care

Study objectives
Proton pump inhibitors are widely prescribed in the National Health Service (NHS) for the treatment of LPR. The data for their efficacy is weak. A study has shown increased efficacy of alginate over no treatment for patients with LPR. We suspect that alginate, either alone or in combination with PPI will show increased efficacy over placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton Local Research Ethics Committee, approval pending as of 07/09/2011

Study design
International multi-centre randomised double-blinded placebo-controlled trial

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Laryngopharyngeal reflux (LPR)

Interventions
1. Patients will receive omeprazole 40 mg or placebo once daily (OD) and
2. Sodium alginate and potassium bicarbonate (Gaviscon® advance) or placebo 5 ml four times a day (QDS) for 6 months

Updated 10/09/2013: this trial has been stopped due to lack of staff/facilities/resources

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)

Omeprazole, sodium alginate and potassium bicarbonate (Gaviscon® advance)

Primary outcome measure
Improvement in validated symptom scores using standardised validated questionnaires. Time points of measurement 2, 4 and 6 months

Secondary outcome measures
1. Laryngeal examination improvement (validated scoring system) at 2 and 6 months in a subgroup of patients
2. Physiological studies (pH / impedance) testing in a subgroup at 2 and 6 months
3. Tissue biopsy pre-treatment and at 2 and /or 6 months

Overall study start date
01/01/2013

Completion date
01/06/2015

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
All adult patients, aged 16 years and over referred from general practice to secondary care who following consultation with an Otolaryngological specialist have a working diagnosis for their symptoms of LPR

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
1500

Key exclusion criteria
1. Children
2. Known or likely upper aerodigestive tract malignancy
3. Pregnancy
4. Known or suspected allergies to any medications used in the trial

Date of first enrolment

01/01/2013

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
Belgium

England

United Kingdom

Study participating centre
CRUK Senior Lecturer in Head and Neck Surgery
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
University Road
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Sponsor type
University/education

Website
http://www.southampton.ac.uk/medicine

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type

Government

Funder Name
Application underway for NIHR Health Technology Assessment Programme - HTA (UK) - Clinical Evaluation and Trials (CET) projects

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