

Drug treatment of Laryngopharyngeal Reflux (LPR)

Submission date 07/09/2011	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/10/2011	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/09/2013	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English Summary

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 hoarseness, 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 subgroup 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
steveframpton@doctors.org.uk

Contact information

Type(s)

Scientific

Contact name

Dr Emma King

Contact details

CRUK Senior Lecturer in Head and Neck Surgery
Cancer Sciences Division
Somers Cancer Research Building
MP824
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

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 hypothesis

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

Condition

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

Overall study end date

01/06/2015

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Participant 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

Participant 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

Recruitment start date

01/01/2013

Recruitment end date

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

Southampton

England

United Kingdom

SO17 1BJ

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