Lansoprazole for persistent throat symptoms in secondary care: the TOPPITS RCT

Janet A Wilson,1,2* Deborah D Stocken,3 Gillian C Watson,4 Tony Fouweather,5 Julian McGlashan,6 Kenneth MacKenzie,7 Paul Carding,8 Yakubu Karagama,9 Meredydd Harries,10 Stephen Ball,11 Sadie Khwaja,12 Declan Costello,13 Ruth Wood,4 Jan Lecouturier2 and James O’Hara1

1Ear, Nose and Throat Department, The Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK
2Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK
3Leeds Institute of Clinical Trials Research, University of Leeds, Leeds, UK
4Newcastle Clinical Trials Unit, Newcastle University, Newcastle upon Tyne, UK
5Biostatistics Research Group, Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK
6Ear, Nose and Throat Department, Nottingham University Hospitals NHS Trust, Nottingham, UK
7Ear, Nose and Throat Department, NHS Greater Glasgow and Clyde, Glasgow, UK
8Oxford Institute of Nursing, Midwifery and Allied Health Research, Oxford Brookes University, Oxford, UK
9Ear, Nose and Throat Department, Manchester University NHS Foundation Trust, Manchester, UK
10Ear, Nose and Throat Department, Brighton and Sussex University Hospitals NHS Trust, Brighton, UK
11Ear, Nose and Throat Department, City Hospitals Sunderland NHS Foundation Trust, Sunderland, UK
12Ear, Nose and Throat Department, Stockport NHS Foundation Trust, Stockport, UK
13Ear, Nose and Throat Department, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK

*Corresponding author j.a.wilson@ncl.ac.uk

Declared competing interests of authors: none

Published January 2021
DOI: 10.3310/hta25030
Plain English summary

Background

One of the commonest reasons for patients attending hospital throat or voice clinics is persistent throat symptoms, which include a feeling of a lump in the throat, a cough or a hoarse voice. Over time, more of these patients are being treated with proton pump inhibitors to suppress stomach acid in the belief that stomach acid entering the throat causes the symptoms, but there is little evidence that these medications work.

Study aim

The aim of this study is to explore whether or not having a 16-week course of proton pump inhibitors has any impact on throat symptoms. We also tested the usefulness of three different questionnaires in measuring throat symptoms, explored side effects and whether or not patients adhere to treatment, and measured patients’ quality of life.

Methods

Patients with persistent (lasting for more than 6 weeks) throat symptoms who agreed to participate were randomised to receive either the proton pump inhibitor lansoprazole or a placebo. Participants took lansoprazole or placebo for 16 weeks. Symptoms and quality of life were measured before patients were randomised and at 4 and 12 months after randomisation.

Results

The total number of participants was 346. The mean Reflux Symptom Index outcome score (higher scores meaning worse symptoms) was 22 before the 4-month course of capsules, 16 after 4 months and 15 after 12 months. Participant-reported throat symptoms and quality of life in all participants improved over the 12 months of the study. There was no difference in the symptom improvement experienced by proton pump inhibitor and placebo participants.

Conclusions

This study shows that proton pump inhibitors do not benefit patients with persistent throat symptoms. Future research should focus on other available therapies.
Criteria for inclusion in the Health Technology Assessment journal

Reports are published in Health Technology Assessment (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in Health Technology Assessment are termed ‘systematic’ when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 12/01/04. The contractual start date was in January 2014. The draft report began editorial review in September 2018 and was accepted for publication in June 2019. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

© Queen’s Printer and Controller of HMSO 2021. This work was produced by Wilson et al. under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).
NIHR Journals Library Editor-in-Chief

Professor Ken Stein  Professor of Public Health, University of Exeter Medical School, UK

NIHR Journals Library Editors

Professor John Powell  Chair of HTA and EME Editorial Board and Editor-in-Chief of HTA and EME journals. Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK, and Professor of Digital Health Care, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Professor Andrée Le May  Chair of NIHR Journals Library Editorial Group (HS&DR, PGfAR, PHR journals) and Editor-in-Chief of HS&DR, PGfAR, PHR journals

Professor Matthias Beck  Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

Dr Tessa Crilly  Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin  Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson  Consultant Advisor, Wessex Institute, University of Southampton, UK

Ms Tara Lamont  Senior Scientific Adviser (Evidence Use), Wessex Institute, University of Southampton, UK

Dr Catriona McDaid  Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

Professor William McGuire  Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads  Emeritus Professor of Wellbeing Research, University of Winchester, UK

Professor James Raftery  Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma  Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts  Professor of Child Health Research, UCL Great Ormond Street Institute of Child Health, UK

Professor Jonathan Ross  Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks  Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Ken Stein  Professor of Public Health, University of Exeter Medical School, UK

Professor Jim Thornton  Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Please visit the website for a list of editors: www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: journals.library@nihr.ac.uk