

Conservative treatment for uncomplicated appendicitis in children: the CONTRACT feasibility study, including feasibility RCT

Nigel J Hall,^{1*} Frances C Sherratt,² Simon Eaton,³ Isabel Reading,⁴ Erin Walker,⁵ Maria Chorozioglou,⁶ Lucy Beasant,⁷ Wendy Wood,⁸ Michael Stanton,⁹ Harriet J Corbett,¹⁰ Dean Rex,¹¹ Natalie Hutchings,¹² Elizabeth Dixon,¹² Simon Grist,¹³ William van't Hoff,⁵ Esther Crawley,⁷ Jane Blazeby¹⁴ and Bridget Young²

¹Faculty of Medicine, University of Southampton, Southampton, UK

²Department of Health Services Research, Institute of Population Health Sciences, University of Liverpool, Liverpool, UK

³University College London Great Ormond Street Institute of Child Health, Department of Population Health Sciences, University College London, London, UK

⁴Primary Care and Population Sciences, Faculty of Medicine, University of Southampton, Southampton, UK

⁵Great Ormond Street Hospital for Children NHS Foundation Trust, London, UK

⁶Southampton Health Technology Assessment Centre, Faculty of Medicine, University of Southampton, Southampton, UK

⁷Centre for Academic Child Health, Bristol Medical School, University of Bristol, Bristol, UK

⁸National Institute for Health Research (NIHR), Research Design Service South Central, University of Southampton, Southampton, UK

⁹Department of Paediatric Surgery and Urology, Southampton Children's Hospital, University Hospital Southampton NHS Foundation Trust, Southampton, UK

¹⁰Department of Paediatric Surgery, Alder Hey Children's NHS Foundation Trust, Liverpool, UK

¹¹Department of Paediatric Surgery, St George's University Hospitals NHS Foundation Trust, London, UK

¹²Southampton Clinical Trials Unit, University of Southampton, Southampton, UK

¹³Patient and public involvement representative

¹⁴Centre for Surgical Research, Population Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK

*Corresponding author n.j.hall@soton.ac.uk

Declared competing interests of authors: Jane Blazeby was a member of the National Institute for Health Research (NIHR) Clinical Trials Unit Standing Advisory Committee between 2015 and 2019. Isabel Reading reports grants from NIHR during the conduct of the study.

Published February 2021

DOI: 10.3310/hta25100

Plain English summary

The CONTRACT feasibility study, including feasibility RCT

Health Technology Assessment 2021; Vol. 25: No. 10

DOI: [10.3310/hta25100](https://doi.org/10.3310/hta25100)

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Plain English summary

Appendicitis is usually treated with an operation to remove the appendix. But we have learned, from other research, that some children with appendicitis may not need an operation, and could be treated with antibiotics instead. To find out how these two different treatments compare with one another, we need to do a big study. First, though, we need to see if doing that kind of study would even be possible (or 'feasible').

We carried out a feasibility study that had several parts. First, we did a small study with children who had appendicitis, whereby children were randomly allocated to have either antibiotics or an operation, with an equal chance of having either treatment. Second, we asked parents and health-care staff about why they wanted, or did not want, to take part in that small study. This helped us to understand how to make a bigger future study as acceptable as possible to children, families and surgeons. Third, we asked parents, patients and surgeons what they think are the most important things – or 'outcomes' – we should look at in future research on children who have appendicitis. From that, we developed a list of outcomes that should be included in our future big study, so we can be certain that the research we do is likely to help parents and surgeons.

Overall, we established that a future big study is feasible and we have plenty of information to help us with how to plan it best, so that it has the greatest possible chance of success.

We were also guided in all of these steps of the research by a group of parents, children and young people, some of whom had appendicitis and some of whom did not.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.370

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, the Cochrane Library and Clarivate Analytics Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

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

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

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 14/192/90. The contractual start date was in July 2016. The draft report began editorial review in January 2019 and was accepted for publication in December 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.

Copyright © 2021 Hall *et al.* This work was produced by Hall *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This is an Open Access publication distributed under the terms of the Creative Commons Attribution CC BY 4.0 licence, which permits unrestricted use, distribution, reproduction and adaptation in any medium and for any purpose provided that it is properly attributed. See: <https://creativecommons.org/licenses/by/4.0/>. For attribution the title, original author(s), the publication source – NIHR Journals Library, and the DOI of the publication must be cited.

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