Immediate oral versus immediate topical versus delayed oral antibiotics for children with acute otitis media with discharge: the REST three-arm non-inferiority electronic platform-supported RCT

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Declared competing interests of authors: Alastair D Hay is a member of the Efficacy and Mechanism Evaluation (EME) Funding Committee (2019–present), is a National Institute for Health Research (NIHR) Senior Investigator (NIHR200151) and is a member of the National Institute for Health and Care Excellence Common Infections Committee. Vibhore Prasad is a NIHR Academic Clinical Lecturer in General Practice (2019–present). Paul Little was a member of the NIHR Journals Library Board while Director of the Programme Grants for Applied Research (PGfAR) programme (2013–18). Anne Schilder is Director of the NIHR Biomedical Research Centre at University College London Hospitals NHS

Foundation Trust and University College London Hearing Theme (London, UK) and is the National Specialty Lead of the NIHR Clinical Research Network Ear, Nose and Throat (ENT); in these roles, Anne Schilder advises companies in the hearing field on the design and delivery of clinical trials. Her evidENT research team at the University College London Ear Institute (London, UK) receives support from various funders, including NIHR, the European Union (EU) Horizon 2020 (Brussels, Belgium) and the Wellcome Trust (London, UK). Roderick Venekamp reports grants from the Netherlands Organisation for Health Research and Development (ZonMw; The Hague, the Netherlands) during the conduct of the study.

Published November 2021
DOI: 10.3310/hta25670

Plain English summary

The REST three-arm non-inferiority RCT

Health Technology Assessment 2021; Vol. 25: No. 67
DOI: 10.3310/hta25670

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Plain English summary

Ear infections are common in childhood. Some are complicated by a burst eardrum, followed by discharge from the ear. The usual treatment for this is a short course of antibiotics taken by mouth. However, alternative treatment using antibiotic drops, or a 'wait and see' policy before starting antibiotics, would result in less antibiotic use and reduce the subsequent risk of antibiotic resistance, which is bad for both patients and the environment.

This study set out to see if these alternative treatments were as effective as the usual treatment for children with ear discharge.

Although ear infections are common, only one in six children develops ear discharge, so only a few children might be available to take part at each general practice. We planned to use an electronic recruitment system to help us to gather enough patients. The system [called the 'TRANSFoRm' (Translational Research and Patient Safety in Europe) platform] was designed to remind busy general practitioners and nurses about the study and take them through the recruitment process step by step, as well as to support trial processes.

Although the TRANSFoRm platform had been developed and tested, it had not been used in general practices before. We were surprised to find that there were many technical problems in setting up the TRANSFoRm platform in general practices, and staff were too busy and/or did not have the skills to overcome the technical issues. As a result, recruiting patients was slow and the study was halted before we had enough children to answer the main research question. In total, we managed to get 44 general practices and 22 children, but this was not enough.

We still think that this kind of research and electronic trial platforms are important. We have noted many system and technical issues that need to be solved to enable funders and researchers to use this recruitment approach in the future.

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Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.014

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

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 16/85/01. The contractual start date was in January 2018. The draft report began editorial review in September 2020 and was accepted for publication in June 2021. 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.

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