Silver-impregnated, antibiotic-impregnated or non-impregnated ventriculoperitoneal shunts to prevent shunt infection: the BASICS three-arm RCT

Conor L Mallucci,1* Michael D Jenkinson,2,3 Elizabeth J Conroy,4 John C Hartley,5 Michaela Brown,4 Tracy Moitt,4 Joanne Dalton,4 Tom Kearns,4 Michael J Griffiths,6,7 Giovanna Culeddu,8 Tom Solomon,6,9 Dyfrig Hughes,8 Carrol Gamble4 and the BASICS study collaborators†

1Department of Paediatric Neurosurgery, Alder Hey Children’s NHS Foundation Trust, Liverpool, UK
2Department of Neurosurgery, The Walton Centre NHS Foundation Trust, Liverpool, UK
3Institute of Translational Medicine, University of Liverpool, Liverpool, UK
4Liverpool Clinical Trials Centre, University of Liverpool, Liverpool, UK
5Department of Microbiology, Great Ormond Street Hospital for Children, London, UK
6Institute of Infection and Global Health, University of Liverpool, Liverpool, UK
7Department of Paediatric Neurology, Alder Hey Children’s NHS Foundation Trust, Liverpool, UK
8Centre for Health Economics and Medicines Evaluation, Bangor University, Bangor, UK
9Department of Neurology, The Walton Centre NHS Foundation Trust, Liverpool, UK

*Corresponding author cmallucci@me.com
†The BASICS study collaborators can be found in Appendix 1.

Declared competing interests of authors: Michael J Griffiths has a patent 068347A1 pending for a novel method of detection of bacterial infection. Tom Solomon reports grants from the National Institute for Health Research (NIHR) outside the submitted work and other support from the Data Safety and Monitoring Committee of the GlaxoSmithKline plc (London, UK) study to evaluate the safety and immunogenicity of a candidate ebola vaccine in children (GSK3390107A) (ChAd3 EBO-Z), outside the submitted work. He also chairs the Siemens Healthineers (Munich, Germany) Clinical Advisory Board. Dyfrig Hughes was member of the Health Technology Assessment (HTA) programme Pharmaceuticals Panel (2008–12) and the HTA programme Clinical Evaluation and Trials board (2010–16). Carrol Gamble reports grants from NIHR outside the submitted work and is a member of the NIHR Efficacy and Mechanism Evaluation programme committee (January 2015–present).
Plain English summary

The BASICS three-arm RCT
Health Technology Assessment 2020; Vol. 24: No. 17
DOI: 10.3310/hta24170

NIHR Journals Library www.journalslibrary.nihr.ac.uk
Plain English summary

Hydrocephalus (commonly known as ‘water on the brain’) is a condition that can affect all age groups, from babies to the elderly. In hydrocephalus, there is an accumulation of the normal brain fluid in the fluid cavities (ventricles) of the brain. Untreated, hydrocephalus can be life-threatening. The most common treatment involves an operation to insert a tube into the swollen ventricles to drain off the excess fluid. This is called a ventriculoperitoneal shunt.

In the UK, 3000–3500 shunt operations are performed each year. The main risks of a shunt operation are infection (surgical meningitis) and blockage without infection. Infection results in the need for at least two further surgeries, antibiotic treatment and a prolonged hospital stay (minimum of 2 weeks). Shunt infections can affect mental abilities and can be life-threatening. People who have blockages without infection, on the other hand, usually need only a single operation to replace the blocked part and only a few days in hospital.

Two new types of shunt catheter have been introduced to try to reduce shunt infection: antibiotic-impregnated shunts and silver-impregnated shunts. This study was designed to assess whether or not either of these new shunts reduce infection compared with standard shunts. This study also included an analysis of the cost and health benefits of the different shunts used.

A total of 1605 children and adults, who were treated in neurosurgical units across the UK and the Republic of Ireland, participated in this study. Consent was provided by all participants in the trial. Each participant had an equal chance of receiving one of the three shunt types.

Shunt infection occurred in 6% of participants receiving standard shunts, 5.9% of participants receiving silver-impregnated shunts and 2.2% of participants receiving antibiotic-impregnated shunts.

This study has demonstrated a major reduction in shunt infections in new shunts when using antibiotic-impregnated shunts compared with standard or silver-impregnated shunts. A health economic analysis has indicated that antibiotic-impregnated shunts are cost-saving.
Health Technology Assessment

ISSN 1366-5278 (Print)
ISSN 2046-4924 (Online)
Impact factor: 3.819

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the 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 10/104/30. The contractual start date was in December 2012. The draft report began editorial review in April 2019 and was accepted for publication in November 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 report 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 2020. This work was produced by Mallucci 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).
Editor-in-Chief of *Health Technology Assessment* and NIHR Journals Library

**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 Senior Clinical Researcher, 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**  Director, NIHR Dissemination Centre, UK

**Dr Catriona McDaidd**  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**  Professor of Wellbeing Research, University of Winchester, UK

**Professor John Norrie**  Chair in Medical Statistics, University of Edinburgh, UK

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

**Dr Rob Riemsma**  Reviews Manager, Kleijnens 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

**Professor Martin Underwood**  Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

Please visit the website for a list of editors: [www.journalslibrary.nihr.ac.uk/about/editors](http://www.journalslibrary.nihr.ac.uk/about/editors)

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