

Sacral nerve stimulation versus the magnetic sphincter augmentation device for adult faecal incontinence: the SaFaRI RCT

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Declared competing interests of authors: David G Jayne reports grants from National Institute for Health Research (NIHR) Senior Investigator awards, and that he was a member of the NIHR Efficacy and Mechanism Evaluation (EME) Strategy Group and Prioritisation Group (2015–18) and NIHR Clinical Scientist Awards Panel (2015–2018). He currently sits on the NIHR Advanced Fellowship Panel (2018 to present) and is a member of the NIHR i4i Product Development Awards Committee (2019 to present). Julia M Brown reports grants from NIHR Senior Investigator awards and the NIHR Funding Committee during the conduct of the study, and declares membership of the Health Technology Assessment (HTA) Remit and Competitiveness Group (2016 to present), Clinical Trial Units funded by NIHR, the HTA Funding Committee Policy Group (2016 to present) and the HTA Clinical Evaluation and Trials Committee (2016 to present). Claire Hulme was a member of the NIHR HTA Commissioning Board (2013–17). Steven Brown was a member of the HTA Commissioning Board (2018–19). David Meads was a member of the NIHR HTA Elective and Emergency Specialist Care (EESC) Methods Group (2014–17) and NIHR HTA EESC Panel (2013–17). He is a member of a NIHR Programme Grants for Applied Research subpanel (2017 to present).

Published March 2021

DOI: 10.3310/hta25180

Plain English summary

The SaFaRI RCT

Health Technology Assessment 2021; Vol. 25: No. 18

DOI: 10.3310/hta25180

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Plain English summary

Faecal incontinence is a distressing condition for patients, and surgery is recommended if symptoms are having an effect on quality of life. One of the treatments recommended for faecal incontinence by the National Institute for Health and Care Excellence is sacral nerve stimulation, which aims to improve continence by stimulating the nerves to the back passage. A newer treatment involves surgery to implant a string of magnetic beads around the anal canal using the FENIX™ device (Torax Medical, Minneapolis, MN, USA). The aim of this study was to assess the benefits and risks of the FENIX device compared with sacral nerve stimulation.

The SaFaRI study aimed to recruit 350 participants with faecal incontinence, but was stopped early because of the manufacturer withdrawing the FENIX device for strategic reasons. In total, we recruited 99 participants. Fifty participants were allocated to receive the FENIX device and 49 participants were allocated to receive sacral nerve stimulation. The observed success rates with both devices were low: at 18 months following their entry into the study, 6 out of 41 (14.6%) participants in the FENIX group and 4 out of 39 (10.3%) participants in the sacral nerve stimulation group had the device both in use and producing a benefit. A total of 5 out of 50 (10.0%) participants allocated to receive the FENIX device did not have a device implanted, and 15 out of 45 (33.3%) participants who did have the FENIX device implanted needed to have it removed because of complications during the 18-month follow-up period. A total of 21 out of 49 (42.9%) participants allocated to receive sacral nerve stimulation did not have a permanent sacral nerve stimulation device implanted, and 0 of the 28 who did have a permanent sacral nerve stimulation device implanted needed to have it removed during the 18-month follow-up period. The costs associated with the FENIX device were higher because of a greater number of participants experiencing complications, meaning that the FENIX device is unlikely to be cost-effective in the treatment of faecal incontinence compared with sacral nerve stimulation.

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.

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 12/35/07. The contractual start date was in January 2014. The draft report began editorial review in June 2019 and was accepted for publication in October 2020. 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.

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