Uterine artery embolisation versus myomectomy for premenopausal women with uterine fibroids wishing to avoid hysterectomy: the FEMME RCT

Jane Daniels,^{1*} Lee J Middleton,² Versha Cheed,² William McKinnon,² Dikshyanta Rana,³ Fusun Sirkeci,⁴ Isaac Manyonda,⁵ Anna-Maria Belli,⁶ Mary Ann Lumsden,⁷ Jonathan Moss,⁷ Olivia Wu³ and Klim McPherson⁸

¹Nottingham Clinical Trials Unit, University of Nottingham, Nottingham, UK ²Birmingham Clinical Trials Unit, University of Birmingham, Birmingham, UK ³Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK ⁴Department of Obstetrics and Gynaecology, Whipps Cross Hospital, London, UK ⁵Department of Gynaecology, St George's Hospital and Medical School, London, UK ⁶Department of Radiology, St George's Hospital and Medical School, London, UK ⁷School of Medicine, University of Glasgow, Glasgow, UK ⁸Department of Primary Care, University of Oxford, Oxford, UK

*Corresponding author jane.daniels@nottingham.ac.uk

Declared competing interests of authors: Jane Daniels is a member of the National Institute for Health and Care Research (NIHR) Clinical Trials Unit Standing Advisory Committee (2016–22). Mary Ann Lumsden reports personal fees from Gedeon Richter plc (Budapest, Hungary) outside the submitted work. Olivia Wu is deputy chairperson (2019) and was member (2016–19) of the NIHR Health Technology Assessment (HTA) General Funding Committee. In addition, Olivia Wu was a member of the NIHR HTA Funding Committee Policy Group (2020–21).

Published April 2022 DOI: 10.3310/ZDEG6110

Plain English summary

The FEMME RCT Health Technology Assessment 2022; Vol. 26: No. 22 DOI: 10.3310/ZDEG6110

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

Plain English summary

What is the problem?

Uterine fibroids are the most common non-cancerous tumour in women of childbearing age. Uterine fibroids are associated with heavy bleeding, lower chances of having children and reduced quality of life. Traditional surgical options were either to remove the fibroids (via myomectomy) or to completely remove the womb. A newer approach, known as uterine artery embolisation, involves blocking the blood supply to the fibroids in the womb.

What did we plan to do?

We compared myomectomy with uterine artery embolisation in women with fibroids who wanted to keep their womb. We wanted to see which treatment improved quality of life, was associated with the fewest complications and was the best value for money for the NHS. We also wanted to see if either treatment had an impact on women's ability to get pregnant and give birth.

We included 254 women in a clinical trial. Women were assigned to have myomectomy or uterine artery embolisation at random to ensure a fair comparison. Women completed questionnaires about their symptoms and quality of life at intervals up to 4 years after treatment.

What did we find?

We found that myomectomy improved women's quality of life more than uterine artery embolisation. Complications from the treatments occurred in a similar proportion of women. There appeared to be no difference on reproductive hormone levels between treatments. Too few women in the trial got pregnant for any difference in the numbers of women having children to be seen. The differences in costs and overall disease burden were small.

What does this mean?

Both treatments improve quality of life and cost about the same to the NHS but, on average, myomectomy will provide greater benefit to women. There is no evidence to suggest that either treatment is unsuitable for women wanting to get pregnant, but more research is needed in younger women.

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.

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 08/53/22. The contractual start date was in June 2011. The draft report began editorial review in June 2020 and was accepted for publication in August 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.

This report presents independent research funded by the National Institute for Health and Care 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, 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 NHS, these of the authors, those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care.

Copyright © 2022 Daniels *et al.* This work was produced by Daniels *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 adaption 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 (HSDR, PGfAR, PHR journals) and Editor-in-Chief of HSDR, 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 Consultant in Public Health, Delta Public Health Consulting Ltd, UK

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

Ms Tara Lamont Senior Adviser, Wessex Institute, University of Southampton, UK

Dr Catriona McDaid Reader in Trials, 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, Child and Adolescent Mental Health, Palliative Care and Paediatrics Unit, Population Policy and Practice Programme, UCL Great Ormond Street Institute of Child Health, London, 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