

The Arabin pessary to prevent preterm birth in women with a twin pregnancy and a short cervix: the STOPPIT 2 RCT

Jane E Norman,^{1*} John Norrie,² Graeme MacLennan,³ David Cooper,³ Sonia Whyte,⁴ Sushila Chowdhry,⁵ Sarah Cunningham-Burley,⁵ Aileen R Neilson,⁵ Xue W Mei,⁶ Joel BE Smith,⁶ Andrew Shennan,⁷ Stephen C Robson,⁸ Steven Thornton,⁹ Mark D Kilby,¹⁰ Neil Marlow,¹¹ Sarah J Stock,⁵ Philip R Bennett¹² and Jane Denton¹³ on behalf of the STOPPIT collaborative group

¹Faculty of Health Sciences, University of Bristol, Bristol, UK

²Edinburgh Clinical Trials Unit, University of Edinburgh, Edinburgh, UK

³Centre for Healthcare Randomised Trials, University of Aberdeen, Aberdeen, UK

⁴Tommy's Centre for Maternal and Fetal Health, MRC Centre for Reproductive Health, University of Edinburgh, Edinburgh, UK

⁵Usher Institute, University of Edinburgh, Edinburgh, UK

⁶Health Economics Research Centre, Nuffield Department of Population Health, University of Oxford, Oxford, UK

⁷Tommy's London Research Centre, King's College London, London, UK

⁸Institute of Cellular Medicine, Newcastle University, Newcastle upon Tyne, UK

⁹Barts and the London School of Medicine and Dentistry, Queen Mary University of London, London, UK

¹⁰Fetal Medicine Centre, Birmingham Women's and Children's NHS Foundation Trust and College of Medical and Dental Science, University of Birmingham, Birmingham, UK

¹¹Institute for Women's Health, University College London, London, UK

¹²Department of Surgery and Cancer, Imperial College London, London, UK

¹³The Multiple Births Foundation, London, UK

*Corresponding author jane.e.norman@bristol.ac.uk

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during the conduct of the study, and declares that he is or has been a member of the following: HTA Commissioning Sub-Board (EOI) (2012–16), NIHR CTU Standing Advisory Committee (2017–present), NIHR HTA and EME Editorial Board (2014–19), Pre-Exposure Prophylaxis Impact Review Panel (2017–present), EME Strategy Advisory Committee (2019–present), EME – Funding Committee Members (2019–present), EME Funding Committee Sub-Group Remit & Comp Check (2019–present), HTA General Committee (2016–19), HTA Funding Committee Policy Group (formerly Clinical Studies Group) (2016–19), HTA Commissioning Committee (2010–16) and was a member of the HTA and EME Editorial Board between 2014 and 2019. Sarah Cunningham-Burley reports personal fees and other from the Wellcome Trust (London, UK), other from the University of Copenhagen (Copenhagen, Denmark), other funding from NIHR Global Health Research, personal fees from the French National Cancer Institute (Paris, France) and personal fees from the Health Research Board (Dublin, Ireland), outside the submitted work. Andrew Shennan is a member of the NIHR HTA Commissioning Committee (2018–22). Stephen C Robson was a member of the NIHR EME Funding Committee (2012–15). Steven Thornton is a trustee of a number of charities, including those that fund related research. He reports personal fees from GlaxoSmithKline plc, during the conduct of the study and outside the submitted work, and personal fees from Johnson & Johnson (Johnson & Johnson, Brunswick, NJ, USA) for consulting services. He holds positions in the Royal College of Obstetricians and Gynaecologists (London, UK) and other organisations. He was a member of the NIHR EME Strategy Advisory Committee (2018–19), EME – Funding Committee Members (2015–19), EME Funding Committee Sub-Group Remit & Comp Check (2018–19) and the Medical Research Council Multimorbidity Board (2020). Neil Marlow reports personal fees from Shire-Takeda (London, UK), Novartis Pharmaceuticals UK Ltd (London, UK) and GlaxoSmithKlein plc, outside the submitted work. Sarah J Stock declares that she is a member of the NIHR HTA General Committee (2016–22). In addition, Sarah J Stock received other research funding from the NIHR (14/32/01 QUIDS), Wellcome Trust (209560/Z/17/Z) and Chief Scientist Office (Edinburgh, UK), during the course of the study. Philip R Bennett reports personal fees and membership of a scientific panel from ObsEva (Plan-les-Ouates, Switzerland), outside the submitted work. In addition, Philip R Bennett has a patent PCT/GB1997/000529 WO1997031631 A1 ‘COX-2 selective inhibitors for managing labour and uterine contractions’ issued, a patent PCT/GB2004/001380 WO2005053705 A1 ‘Use of a cyclopentenone prostaglandin for delaying the onset and/or preventing the continuation of labour’ (priority date 2 December 2003) issued, a patent PCT/GB2016/050618 ‘Circulating miRNAs predictive of cervical shortening and preterm birth’ (pending UK filing 6 March 2015/full international filing completed 7 March 2016) issued, a patent PCT/GB2016/050621 ‘Rapid evaporative ionisation mass spectroscopy (REIMS) and desorption electrospray ionisation mass spectroscopy (DESI-MS) analysis of swabs and biopsy samples’ (pending UK filing 6 March 2015/full international filing completed 7 March 2016) pending, a patent PCT/GB2019 ‘Desorption electrospray ionisation mass spectroscopy (DESI-MS) analysis of swabs to predict vaginal microbiota’ (pending UK filing March 2019) pending, and a patent PCT/GB2019/ ‘Circulating miRNAs predictive of IUGR’ (pending UK filing March 2019) pending.

Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Plain English summary

The STOPPIT 2 RCT

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Plain English summary

Women who are pregnant with twins have a much higher risk of going into labour early and having an early (preterm) birth than women who are pregnant with only one baby. For this reason, babies who are twins are much more likely to die or to have serious health complications in the first months of life.

Although we know that women with twin pregnancy are at risk, there are no treatments that are recommended to prevent early births.

Some studies have suggested that the Arabin pessary can help. The Arabin pessary is a silicone ring that fits around the cervix (neck of the womb). The pessary can be put in place in a clinic without any need for an anaesthetic.

Some studies have suggested that the Arabin pessary helps and others have suggested that it does not. It appears to be most helpful when the cervix (neck of the womb) is already shortening. Shortening of the neck of the womb is a sign that early birth is even more likely.

We asked women with twin pregnancy to take part in STOPPIT 2. Women who agreed had an ultrasound scan of the neck of the womb, which measured its length. Those with a short cervix were randomised to be offered the Arabin pessary (in addition to standard care) or standard care alone. This allocation was carried out 'at random' by a computer.

We followed women up until the end of their pregnancy and collected information on the babies' health after birth.

We found that the Arabin pessary did not reduce the risk of an early birth; nor did it reduce the risk of health complications for the baby. We conclude that the Arabin pessary should not be used for this purpose.

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This report

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