# Partial ablation versus radical prostatectomy in intermediate-risk prostate cancer: the PART feasibility RCT

Freddie C Hamdy, 1\* Daisy Elliott, 2 Steffi le Conte, 1 Lucy C Davies, 3 Richéal M Burns, 3 Claire Thomson, 1 Richard Gray, 3 Jane Wolstenholme, 3 Jenny L Donovan, 2,4 Ray Fitzpatrick, 3 Clare Verrill, 1 Fergus Gleeson, 5 Surjeet Singh, 1 Derek Rosario, 6 James WF Catto, 5 Simon Brewster, 7 Tim Dudderidge, 8 Richard Hindley, 9 Amr Emara, 9 Prasanna Sooriakumaran, 10 Hashim U Ahmed 11 and Tom A Leslie 1

<sup>1</sup>Nuffield Department of Surgical Sciences, University of Oxford, Oxford, UK

**Declared competing interests of authors:** Ray Fitzpatrick is a member of the Health Technology Assessment Priority Research Advisory Methods Group. Richard Hindley has received payments for lecturing and proctoring for SonaCare Medical (Charlotte, NC, USA; high-intensity focused ultrasound treatment). Hashim U Ahmed reports grants and personal fees from SonaCare Medical and grants from Trod Medical (Heverlee, Belgium) and Sophiris Bio Inc. (La Jolla, CA, USA) outside the submitted work.

Published September 2018

DOI: 10.3310/hta22520

<sup>&</sup>lt;sup>2</sup>Population Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK

<sup>&</sup>lt;sup>3</sup>Nuffield Department of Population Health, University of Oxford, Oxford, UK

<sup>&</sup>lt;sup>4</sup>National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care West at University Hospitals Bristol NHS Foundation Trust, Bristol, UK

<sup>&</sup>lt;sup>5</sup>Department of Oncology, University of Oxford, Oxford, UK

<sup>&</sup>lt;sup>6</sup>Department of Oncology and Metabolism, University of Sheffield, Sheffield, UK

<sup>&</sup>lt;sup>7</sup>Oxford University Hospitals NHS Foundation Trust, Oxford, UK

<sup>&</sup>lt;sup>8</sup>University Hospital Southampton NHS Foundation Trust, Southampton, UK

<sup>&</sup>lt;sup>9</sup>Hampshire Hospitals NHS Foundation Trust, Basingstoke, UK

<sup>&</sup>lt;sup>10</sup>University College London Hospitals NHS Foundation Trust, London, UK

<sup>&</sup>lt;sup>11</sup>Department of Surgery and Cancer, Imperial College London, London, UK

<sup>\*</sup>Corresponding author freddie.hamdy@nds.ox.ac.uk

## **Plain English summary**

## The PART feasibility RCT

Health Technology Assessment 2018; Vol. 22: No. 52 DOI: 10.3310/hta22520

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

## **Plain English summary**

Men with prostate cancer that is thought to significantly affect only one area of the prostate gland may be offered treatment of the whole gland, including surgery to remove the prostate, or radiotherapy. These treatments have side effects, including leaking urine and difficulty getting an erection, so another option is repeat investigations at regular intervals (active surveillance), with surgery or radiotherapy undertaken only if the cancer progresses.

High-intensity focused ultrasound (HIFU) is a new treatment that targets only the areas of cancer using sound waves directed at the tissues containing significant cancer, causing them to heat up and die. HIFU may be just as good at preventing progression as treating the whole prostate, with fewer side effects, but research is needed to be sure of this.

Partial prostate Ablation versus Radical prosTatectomy (PART) is a feasibility study comparing HIFU (treating only part of the prostate) with surgery (removing the whole prostate) in men with cancer in only one area of their prostate gland that has a medium risk of spreading elsewhere over the next few years, and so treatment is recommended.

The PART trial aimed to find out if men would be willing to take part in such a study. If they were, the same research could be done with a large number of men to find out whether or not HIFU is as good as surgery in preventing prostate cancer from spreading, and what the short-, medium- and long-term side effects of each treatment are.

The feasibility study was conducted successfully and reached its target of recruiting 80 participants. Men filled out questionnaires about side effects and their quality of life before treatment and a further eight times over the following 3 years to help the research team understand how the different treatments affected them. We have therefore shown that a large trial to provide definitive evidence is possible, and essential, before practice can change for the benefit of patients.

#### HTA/HTA TAR

## **Health Technology Assessment**

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.513

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

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

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.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

#### This report

The research reported in this issue of the journal was funded by the HTA programme as project number 12/35/54. The contractual start date was in January 2015. The draft report began editorial review in May 2017 and was accepted for publication in November 2017. 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.

© Queen's Printer and Controller of HMSO 2018. This work was produced by Hamdy 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).

#### **NIHR Journals Library Editor-in-Chief**

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the EME Programme, UK

#### **NIHR Journals Library Editors**

**Professor Ken Stein** Chair of HTA and EME Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andrée Le May Chair of NIHR Journals Library Editorial Group (HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

**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 Director of the NIHR Dissemination Centre, University of Southampton, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

**Dr Catriona McDaid** 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 John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), 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, 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 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

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