

TARVA Newsletter

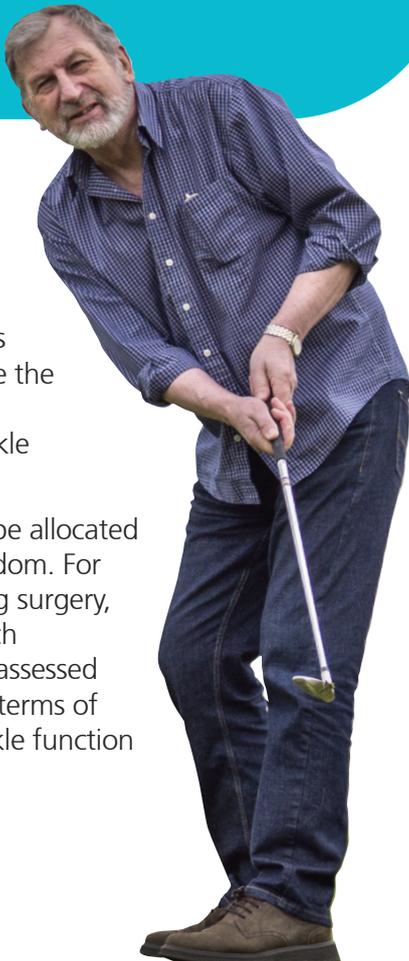
RANDOMISED CLINICAL TRIAL



TARVA is a clinical trial for patients with ankle arthritis who are considering surgery

TARVA stands for Total Ankle Replacement Versus Arthrodesis (fusion), which are the two main surgical treatments for ankle arthritis.

Surgery type will be allocated to patients at random. For one year following surgery, the success of each operation will be assessed and compared in terms of each patient's ankle function and quality of life.



*Randomisation in the TARVA trial refers to the random allocation of a surgery type to a patient.

To learn more about the TARVA Trial please visit our website www.anklearthritis.co.uk or follow us on Twitter @TARVA_Trial

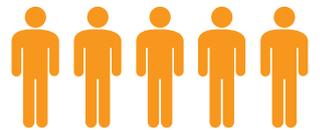
Funding

This trial has been funded by the National Institute of Health Research (NIHR) Health Technology Assessment (HTA) Programme - HTA Project: 12/35/27

News

First patients randomised*

The first five patients in the TARVA trial have been allocated a surgical procedure. 323 more to go.



Four sites actively recruiting

Royal National Orthopaedic Hospital, Aintree University Hospital, Wrightington Hospital and Sheffield's Northern General Hospital are now recruiting patients.

Find your nearest TARVA Hospital here



TARVA Twitter
@TARVA_Trial
reaches over 820 followers.



TARVA presented at the Royal College of Surgeons Orthopaedic Trials Day

TARVA investigators attended talks from leading researchers and research funders, and had the opportunity to discuss challenges facing surgical trials.



More details on page 4

TARVA featured in Orthopaedic Product News

The award-winning TARVA video (**view here**) was featured in a leading magazine written by practitioners in the field of orthopaedics.



The TARVA Trial from the Patients' Perspective

We are delighted that some of TARVA's first ever recruits have agreed to tell us why they have become involved.

I spent a year trying to manage the condition without resorting to surgery. I lost weight, got shoe inserts, used an ankle brace, pain killers, gels and a TENS machine. I also modified my lifestyle significantly and it was the realisation that I was making too many sacrifices that got me thinking about the possibility of surgery.

The information I was given about TARVA was useful and easy to understand.

I am most looking forward to getting back to the eternal quest to lower my golf handicap, taking a Caribbean cruise with my wife, getting to grips with my garden without fear of stumbling on uneven ground, and not shovelling down pain killers.

Having retired relatively recently, I was looking forward to three things; lot of walking, gardening and, especially, golf. My arthritis has significantly impacted my ability to do all three.

I fell down a small step and broke my ankle in several places.

I wanted to take part in the TARVA trial for 3 reasons: first and foremost I wanted to get treatment which would hopefully allow me to resume some of the activities I have relinquished; secondly because there was an opportunity to contribute to, and participate in, an important piece of medical research; and thirdly, because I genuinely couldn't decide whether a replacement or arthrodesis was the best option for me and so I'm happy for a computer to make the choice for me!

I tried 10 months of physiotherapy, exercise and injections before I considered surgery.

I heard about the TARVA trial on Radio 4 and then looked it up on the Internet.

I have some concerns about not knowing for some time what operation I will have.

My ankle arthritis means that I struggle with simple things like going two steps up a ladder to open a window or getting something from the top of a cupboard.

Once I decided I might need surgery, I spoke to my consultant Mr Kurup at the Pilgrim Hospital, Lincolnshire, who recommended the TARVA trial to me and I was happy to take his advice. He thought it would be a good option.

I had arthroscopy surgery in 2011 and another operation in 2013 but these didn't work.

I am looking forward to starting my life again and being able to wear a pair of very nice shoes and a dress and skirt instead of a cast boot and leggings.

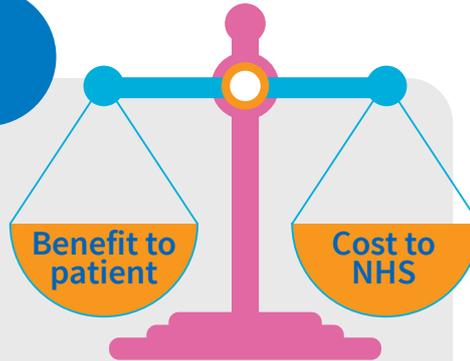
I just feel that I am in good hands and anyway both fusion and replacement are equally recommended for my case.

The first three TARVA recruits (from left to right): Karen Porter, David Shaw and Julie Dawson.



Focus on Health Economics

One of the main challenges faced by the NHS is how to provide the best quality healthcare within a fixed NHS budget. **Health Economists try to answer this question by looking at two things:**



1. How much it costs to provide a treatment.

We measure all of the costs involved in providing the treatment and we try to include the care people receive beyond the NHS. In the TARVA study we are asking participants to tell us about their use of social services and any money they spend themselves on care.

2. The benefits of the treatment to the patient.

This refers to the impact treatment has on the quality of life of a patient. To do that we ask questions about a patient's health using a questionnaire called the EQ-5D, which allows comparison of the benefits of treatments across different patient groups.

Generally speaking, by measuring the impact of treatment on quality of life, we can determine which treatments should be funded by the NHS.

The TARVA Health Economist



Jeff Round is the head of the Health Economics team at UCL's Comprehensive Clinical Trials Unit and leading the TARVA health economic analysis. Jeff has been involved in health economics research and teaching for over ten years. His research has covered areas as varied as obstetrics and maternal health, palliative care and surgery.

Meet the Trial Steering Committee

The role of a Trial Steering Committee (TSC) is to provide oversight and advice on all aspects of the trial. The rights, safety and well-being of the trial participants are the most important consideration for the committee and will prevail over the interests of science and society. The TSC includes members of the Trial Management Group. Here we meet the TSC's Patient & Public Representative and the other independent members:

Mr Nick Welch

TARVA Patient and Public Representative, British Orthopaedic Association

Nick spent 35 years in the Pharmaceutical Industry working in sales and marketing throughout the EU before retiring in 2006. He is a member of the British Orthopaedic Association's Patient Liaison Group and represents patients in several NICE and NHS England Groups.



Professor Amar Rangan, Chair

Professor of Orthopaedic Surgery, Durham University & The James Cook University Hospital



Dr Stephen Brealey

Trial Coordinator, University of York



Professor Marion Campbell

Statistician, Health Services Research Unit Director, University of Aberdeen



Professor Alison McGregor

Professor of Musculoskeletal Biodynamics, Imperial College London



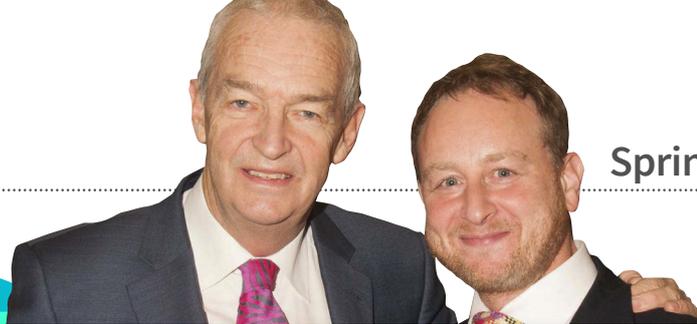
Professor Nachi Chockalingam

Professor of Clinical Biomechanics, Staffordshire University



Professor Hamish Simpson

Professor of Orthopaedics and Trauma, University of Edinburgh



Orthopaedic Trials Day

Monday 17th March 2015
at The Royal College of Surgeons of England, London



“The UK is a world-leader in surgical trials. Orthopaedics is being challenged on the level of evidence for certain procedures.”

Professor Amar Rangan



Photos courtesy of Jan Letocha.

Other talks included:

- **Challenges in surgical trials** - Professor Andy Carr discussed outcomes that really matter to patients, the importance and role of the placebo effect* and how to get surgeons to change their practice in response to the evidence.
- **Understanding and improving recruitment** - Professor Jenny Donovan explored how to prevent research disrupting clinical practice and the doctor-patient relationship.
- **Clinical Research Network (CRN) Support** - Dr Jonathan Gower expanded on the £284 million of research support infrastructure that is available each year to facilitate trial recruitment to time and target. He also explained how the CRN wishes to build a network of research-ready hospitals with expertise in surgical trials.
- **Trial monitoring - a funder's perspective** - Dr Andrew Cook from the Health Technology Assessment programme, which funds up to 400 trials including TARVA, emphasised that clear communication between trial teams and the funder about the running and results of trials is essential.

The TARVA, C|SAW, and UKFROST trial teams organised brainstorming breakout sessions to come up with: ways to ensure equipoise** ; innovations to facilitate recruitment to target; and methods to raise the local and national profile of surgical research.

* Placebo effect refers to the phenomenon of an inactive treatment resulting in an improvement in how people feel.
** Equipoise means that there is genuine uncertainty over which treatment is most beneficial.

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If you have a story or case study you would like included in a future newsletter please let us know at tarvanewsletter@rnoh.nhs.uk
www.anklearthritis.co.uk @TARVA_trial

Ms Claire Thomson
Newsletter Sub-Editor

Mr Andrew Goldberg
Newsletter Advisor

The day was co-sponsored by the UCL Comprehensive Clinical Trials Unit (CTU), alongside the CTU's from York and Oxford and the Royal College of Surgeons.

In the Summer newsletter:

- 1) A patient's story
- 2) Randomisation explained
- 3) Meet the Independent Data Monitoring Committee