

TARVA Newsletter

RANDOMISED CLINICAL TRIAL



TARVA is a clinical trial for patients with ankle osteoarthritis (OA) that are considering surgery.

Ankle arthritis is a disabling condition that causes pain and stiffness and affects quality of life as much as end stage heart failure. Nearly 30,000 patients consult specialists for this condition in the UK each year.

TARVA stands for Total Ankle Replacement Versus Arthrodesis, and so is comparing the two main surgical treatments for ankle arthritis and which offers the best outcome for patients.

There has never been a randomised trial directly comparing the two procedures.

The results of the study, being funded by the National Institute for Health Research (NIHR), will provide high quality evidence to help patients and their surgeons to choose between the two procedures, and inform commissioning decisions in the NHS.



News

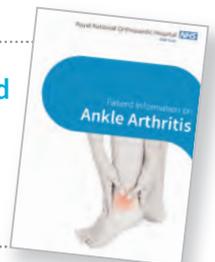
Tarva wins prestigious national award

The TARVA video has beaten off fierce competition to win the National NIHR New Award for best video to encourage recruitment and patient education in a clinical trial. **View here**



Patient Information Brochure launched

Our Ankle Arthritis brochure has been launched to much positive feedback from patients. **Read here**



TARVA Twitter

TARVA twitter has launched **@TARVA_Trial** and has already achieved 80 followers in its first few weeks.



TARVA on Radio 4

TARVA promoted to over 1m listeners on Dr Mark Porter's Inside Health. **Listen here**



TARVA in Daily Mail

TARVA features in Daily Mail reaching close to 2m readers. **Read here**



Arthritis Care

Arthritis Care have put a link to TARVA on their website. **View here**



Find out more: www.anklearthritis.co.uk

Meet the team... your main trial contacts

If you have any questions please
e-mail us at tarva@rnoh.nhs.uk
or follow us @TARVA_Trial



Mr Andrew Goldberg
Chief Investigator &
Foot & Ankle Surgeon



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TARVA Trial Manager



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Radiologist
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Mrs Deirdre Brooking
Clinical Research
Coordinator, RNOH



Dr Elin Rees
TARVA Data Manager

Mrs Marion Cumbers

TARVA Trial Patient Representative

Marion has been a patient representative since 2004 through her involvement with the Royal National Orthopaedic Hospital (RNOH) CPPIH Patient Forum. She is also a lay member of the North London (Stanmore) Research Ethics Committee and contributes patient views to other medical groups. Marion's varied interests include foreign travel, mountain walking and her six grandchildren.



Pilot Sites

We are excited to announce that four pilot sites, RNOH (Stanmore), Aintree University Hospital, Wrightington Hospital and Northern General Hospital (Sheffield), will start recruiting to the TARVA Trial from January 2015.

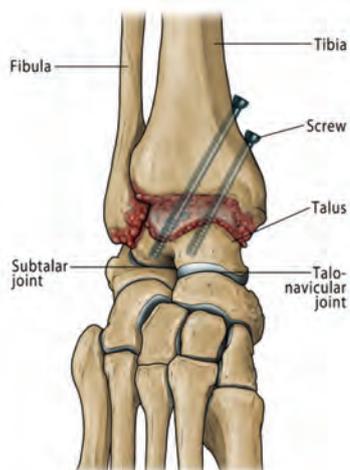
Future TARVA Sites

These pilot sites will be joined later in the year by more hospitals nationwide. These may include:

- ✓ Brighton & Sussex University Hospitals NHS Trust
- ✓ Cambridge University Hospitals NHS Foundation Trust
- ✓ Derby Hospitals NHS Foundation Trust
- ✓ NHS Greater Glasgow and Clyde
- ✓ Hull & East Yorkshire Hospitals NHS Trust
- ✓ Leeds Teaching Hospital NHS Trust
- ✓ Newcastle Upon Tyne Hospitals NHS Foundation Trust
- ✓ Norfolk and Norwich University Hospitals NHS Foundation Trust
- ✓ North Bristol NHS Trust
- ✓ Nottingham University Hospitals NHS Trust
- ✓ Northumbria Healthcare Foundation NHS Trust
- ✓ Oxford Radcliffe Hospitals NHS Trust
- ✓ Robert Jones and Agnes Hunt NHS Foundation Trust
- ✓ Royal Devon & Exeter NHS Foundation Trust
- ✓ Royal Surrey County Hospital NHS Foundation Trust
- ✓ South Devon Healthcare NHS Foundation Trust
- ✓ University Hospital of Wales NHS Trust

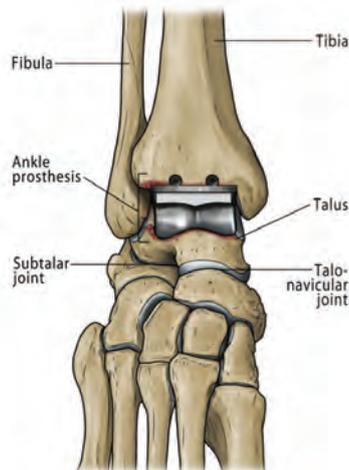


About the Treatments



Ankle fusion removes damaged cartilage from the ends of the bones and holds them together using screws or plates until they join to become one (bone fusion).

Read more



Total ankle replacement is an operation to remove damaged cartilage from the ends of the bones and replace this with metal and plastic implants to allow gliding motion.

Read more

Independent Data Monitoring Committee

Independent experts, Professors Hurley, Cobb and Sharples, sit on the Independent Data Monitoring Committee (IDMC) whose role is to review the 6-month pilot phase data and decide, based on recruitment rates and other data, whether to progress from the feasibility phase to the full trial.

Editorial team contact details

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Newsletter Editor

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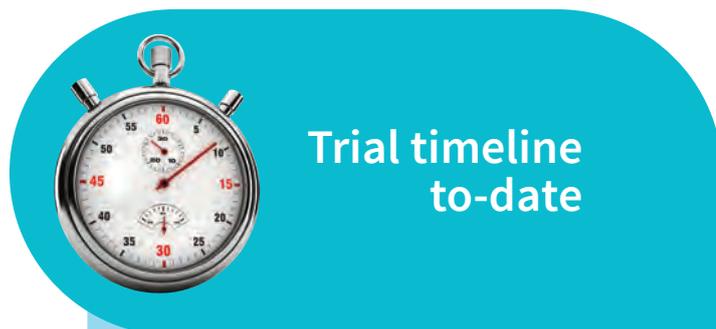
Mrs Marion Cumbers
Newsletter Patient Representative

Mr Andrew Goldberg
Newsletter Advisor

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

Funding

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



Trial timeline to-date

April 2013

Grant application approved by NIHR Health Technology Assessment (HTA)

March 2014

Grant activated

June 2014

Protocol approved by National Research Ethics Service (NRES) Committee London - Bloomsbury (14/LO/0807)

August 2014

First IDMC & Steering Committee meeting

October 2014

Lead site obtained local Research & Development (R&D) approval

November 2014

Investigator Meeting in Brighton

November 2014

First site initiation visit performed in Aintree

January 2015

Pilot sites will be activated*:

Recruitment starts

*Before site initiation and activation the Site Agreement must be signed and the Site-Specific Information form must be completed and approved by local R&D offices.



TARVA Investigator Meeting
Brighton, 4th November 2014



Thank you to all those who were able to attend and make this meeting a success. We really value your support and contributions.

Discussion points

“ Clinic **space requirements**
- separate room needed to give trial information.

“ Timing of **pre-op MRI scan**
- MRI must be within 6 months of surgery.

“ **Adverse events** are defined as any new or worsening medical problems, and should be reported if they are over and above what would normally be expected after ankle surgery.

“ Timing of **pre-op assessment**
- sites to develop local processes.

“ NHS patients operated on in **private hospitals** may be considered for recruitment, with agreement from UCL.

“ **Mr Mark Glazebrook** (Foot & Ankle Surgeon, Canada) discussed his Canadian research experiences.

“ Full tibia **x-rays** should be weight-bearing.

“ TARVA patient **contact card** to be provided.

Coming in the Spring newsletter:

- 1) Meet the Trial Steering Committee
- 2) What is health economics?
- 3) A patient's perspective