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Total Ankle Replacement Versus Arthrodesis (TARVA) Trial

Submission date
01/05/2014

Recruitment status
No longer recruiting

Registration date
12/05/2014

Overall study status
Completed

Last Edited
09/01/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ankle osteoarthritis (OA) is a condition where the lining cartilage of the ankle joint has worn away, either because of injury or inflammation (such as rheumatoid arthritis). It causes progressive pain and stiffness. In the early stages of disease treatments such as change in activity levels, weight loss, physiotherapy, painkillers and ankle braces should be used. When these measures have failed, and providing the surgeon confirms the diagnosis of osteoarthritis (now termed end-stage OA), surgery might then be considered. The main surgical treatments for end-stage ankle OA are ankle arthrodesis (fusion) or total ankle replacement (TAR). Ankle fusion is the most common surgical treatment but patients are increasingly requesting TAR and so the number of surgeons taking up this procedure is also increasing. About 3,000 patients undergo ankle fusion or TAR in the NHS each year, with much variation in practice across the country. Both treatments are available on the NHS, and both have been reported to have good results. Some studies suggest that TAR restores a more natural walking pattern than ankle fusion but other studies have suggested that the need for further surgery is higher with TAR than with fusion. There has never been a study directly comparing the two treatments and therefore it is difficult to recommend the best procedure for a patient. Hence we propose to compare TAR with ankle fusion.

Who can participate?
Patients aged between 50-85 years with end-stage ankle OA can take part.

What does the study involve?
Patients will be randomly allocated to one of the two surgical strategies, TAR or ankle fusion, on an equal basis (164 patients per group). Patients will be told which treatment they will receive at their pre-operation assessment appointment 2-6 weeks before surgery. Patients will be asked to attend hospital appointments to have clinical assessments and complete questionnaires about general health and well-being, pain, physical function before their operation, and at 6, 12, 26 and 52 weeks after surgery. Beyond the end of the study, patients who give consent will be sent questionnaires at 2, 5 and 10 years so that information on long-term outcomes can be collected.

What are the possible benefits and risks of participating?
Although there are no direct benefits to patients for participating, we hope that the information

we get from this study will help improve the treatment of people with ankle arthritis in the future. As both treatments are already available on the NHS, and surgeons will use exactly the same technique that they would normally use and the same post-operative care, there are no additional risks to patients by taking part in this study.

Where is the study run from?
The study will take place in the UK at the following sites:

Royal National Orthopaedic Hospital NHS Trust, Stanmore
Aintree University Hospitals NHS Foundation Trust
Cambridge University Hospitals NHS Trust
Glasgow Royal Infirmary, NHS Greater Glasgow and Clyde
Leeds General Infirmary, Leeds Teaching Hospitals 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
Oxford University Hospitals NHS Trust
Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Trust
Sheffield Teaching Hospitals NHS Foundation Trust
South Devon Healthcare NHS Foundation Trust
University Hospital of Wales NHS Trust, Cardiff
Wrightington, Wigan and Leigh NHS Trust

Please note that sites will be incorporated to the study in stages, so not all sites will be recruiting patients from the start of the study.

When is the study starting and how long is it expected to run for?
The study starts in December 2014 and runs until May 2018.

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Mr Andy Goldberg, andy.goldberg@nhs.net

Contact information

Type(s)
Scientific

Contact name
Mr Andy Goldberg

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02128555

Secondary identifying numbers
U1111-1157-4155

Study information

Scientific Title
A randomised, multi-centre, non-blinded, prospective, parallel group trial of total ankle replacement (TAR) versus ankle arthrodesis in the treatment of patients with end stage ankle osteoarthritis, comparing clinical outcomes and cost-effectiveness

Acronym
TARVA

Study objectives
TARVA aims to compare total ankle replacement with arthrodesis to determine which surgical treatment offers better clinical outcomes for patients and value for money for the NHS.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/123527
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/123353/PRO-12-35-27.pdf

On 08/10/2014 the anticipated start date was changed from 01/07/2014 to 01/12/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Bloomsbury Research Ethics Committee, favourable opinion received on 10/06/2014 with additional conditions met on 20/06/2014, ref. 14/LO/0807. Ethics approval was granted for the amendment on 26/09/2014

Study design
Randomized multi-centre non-blinded prospective parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
After consenting to join the study, patients will have a Magnetic Resonance Imaging (MRI) scan (or Computed Tomography [CT] scan where they have contraindications to an MRI scan) in order to assess whether they have osteoarthritis in the two joints adjacent to the ankle. Patients will be randomised on an equal basis to either Total Ankle Replacement (TAR) or arthrodesis (fusion), and randomisation will be stratified (balanced) by surgeon, and presence of osteoarthritis in the adjacent joints. Patients will be randomly allocated to a treatment at their pre-operation assessment appointment, approximately 2 to 6 weeks before their operation date, and will undergo their allocated surgical procedure within 90 days of consenting to join the study.

1. Total Ankle Replacement (TAR): The joints are resurfaced with metal implants and a mobile plastic liner is placed between them as the gliding surface.
2. Ankle Arthrodesis (Fusion): The remaining damaged cartilage is removed from the ends of the bone and the two bones are then held together in compression using screws, or plates until they join to become one (bone fusion), so that there is no longer any movement at that joint.

Patients will be followed up for one year after their surgical treatment when they attend routine post-operation hospital appointments at 2, 6, 12, 26 and 52 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Improvement in self-reported pain-free function from pre-op to 26 weeks post-op for TAR versus arthrodesis, assessed by MOXFQ walking/standing domain scores.

Secondary outcome measures
1. Improvement in self-reported pain and social interaction domain scores from pre-op to 26 and 52 weeks post-op for TAR versus arthrodesis, assessed by MOXFQ.
2. Improvement in self-reported physical function from pre-op to 26 and 52 weeks post-op of TAR versus arthrodesis, assessed by the Foot and Ankle Ability Measure (FAAM) questionnaire.
3. Improvement in QoL from pre-op to 26 and 52 weeks post-op of TAR versus arthrodesis, assessed by EQ-5D.
4. Change in total range of movement (plantarflexion and dorsiflexion) from pre-op to 52 weeks

post-op of TAR versus arthrodesis, assessed by goniometer.
5. Safety of TAR versus arthrodesis in terms of complications and adverse events.
6. Incremental cost and outcomes of TAR versus arthrodesis. We will record the cost of all surgical components and procedure-related costs for each treatment. This will be supplemented with patient self-reported data collected using a modified version of the Client Services Receipt Inventory (CSRI) questionnaire. Outcomes will be measured using the EQ-5D. The CSRI and EQ-5D will administered at baseline, 12, 26 and 52 weeks to allow comparison of changing resource use patterns over time.

Overall study start date
01/12/2014

Completion date
14/05/2018

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/10/2014:
1. Diagnosis of end-stage ankle OA
2. Aged 50-85 years inclusive
3. The surgeon believes the patient is suitable for both TAR and arthrodesis (having considered deformity, stability, bone quality, soft tissue envelope, and neurovascular status)
4. The patient is able to read and understand the Patient Information Sheet (PIS) and trial procedures
5. The patient is willing and able to provide written informed consent

Previous inclusion criteria:
1. Diagnosis of end-stage ankle OA
2. Aged 50-85 years inclusive
3. The surgeon believes the patient is suitable for both TAR and arthrodesis
4. The patient is able to read and understand the Patient Information Sheet (PIS) and trial procedures
5. The patient is willing and able to provide written informed consent

Participant type(s)
Patient

Age group
Senior

Lower age limit
50 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
328

Total final enrolment
303

Key exclusion criteria
Current exclusion criteria as of 08/10/2014:
1. Previous ipsilateral talonavicular, subtalar or calcaneocuboid fusion or surgery planned within 1 year of index procedure
2. More than four lower limb joints fused (including contralateral limb, but excluding proximal interphalangeal joint fusions)
3. Unable to have MRI/CT scan (e.g., severe claustrophobia or contraindication for either scan)
4. History of local bone or joint infection
5. Any co-morbidity which, in the opinion of the investigator, is severe enough to interfere with the patients ability to complete the study assessments or presents an unacceptable risk to the patients safety
6. Participant in another clinical trial that would materially impact on their participation in this study

Previous exclusion criteria:
1. Previous ipsilateral talonavicular, subtalar or calcaneocuboid fusion or surgery planned within 1 year of index procedure
2. More than four lower limb joints fused (including contralateral limb)
3. Significant deformity (>20 degrees at tibiotalar joint) on standing films
4. Ligamentous disruption (with clinical instability)
5. Unable to have MRI/CT scan (e.g. severe claustrophobia or contraindication for either scan)
6. Poorly controlled diabetes (HbA1c>9)
7. Poor vascular supply or soft tissue envelope
8. Above 15% AVN of the talus
9. History of local infection
10. Pregnancy (in women of childbearing potential)
11. Severe osteoporosis (T Score <-2.5) with recent fracture (<12 months)
12. Any co-morbidity (e.g., diabetes, heart condition, obesity, active cancer, psychiatric illness, hypermobility syndrome etc) which, in the opinion of the investigator, is severe enough to interfere with the patients ability to complete the study assessments or presents an unacceptable risk to the patients safety
13. The patient has participated in a clinical trial and has had an investigational medicinal product (IMP) administered within the last 3 months, or is currently participating in a clinical trial of a medical device

Date of first enrolment
01/12/2014

Date of final enrolment
14/05/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Orthopaedics and Musculoskeletal Sciences
Stanmore
United Kingdom
HA7 4LP

Sponsor information

Organisation
University College London (UCL) (UK)

Sponsor details
c/o Susan Tebbs
Comprehensive Clinical Trials Unit at UCL
Institute of Clinical Trials Methodology
London
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WC1E 6BT

Sponsor type
University/education

Website
http://www.ucl.ac.uk/cctu

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK); Ref. 12/35/27

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/09/2016	10/04/2019	Yes	No
Statistical Analysis Plan	statistical analysis plan	18/02/2020	24/02/2020	No	No
Results article		15/11/2022	15/11/2022	Yes	No
Results article		01/03/2023	11/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Cost-utility analysis	08/01/2024	09/01/2024	Yes	No