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A randomised trial of ankle joint replacements

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 19/10/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0284126103

Study information

Scientific Title

Study objectives

To compare the long term performance of ankle joint replacements - STAR and BP. Current literature states that there is no long term difference between the two prosthesis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery: Ankle replacement

Interventions
Long term follow up, in terms of range of motion, x-ray assessment and gait analysis on selected patients. Recruit over two years and follow up for 10 years

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
A long term clinical comparison of two ankle replacements

Key secondary outcome(s)
Not provided at time of registration

Completion date
03/01/2010

Eligibility

Key inclusion criteria
Patients with Scandinavian Total Ankle Replacement (STAR) and Buechel-Pappas (BP) total ankle replacements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
03/01/2000

Date of final enrolment
03/01/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wrightington, Wigan & Leigh NHS Trust, Wright
Wigan
United Kingdom
WN6 9EP

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name

Wrightington, Wigan and Leigh NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2009		Yes	No