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Outcomes in using biodegradable fixation materials for fractures of the ankle

Submission date	Recruitment status	[ ] Prospectively registered
13/05/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/11/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/11/2012	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
08/H1005/47

Study information

Scientific Title
The use of biodegradable fixation system for closed fractures of the ankle

Study objectives
There is a clinical difference in using biodegradable fixation methods in ankle fractures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the Liverpool Adult Local Ethics Committee on the 22nd September 2008 (ref: 08 /H1005/47).

Study design
Randomised controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Closed fractures of the ankle

Interventions
All patients who meet the inclusion criteria will be identified on admission and given the choice of entering the trial at which point they will sign a consent form. Patients can exit the trial at any point. Two cohorts of patients will exist, those for traditional fixation with a neutralisation plate, screws and medial malleolar screws, and there will also be those who have the biodegradable implants used.

Randomisation will be done using block randomisation. Four treatments, two of each kind, will be allocated to the block. All combinations for the order of treatment will be included. Consequently there will be six blocks. A random number generator will then be use to allocated a block of treatment to each sequence of four successive patients.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
1. The American Orthopaedic Foot and Ankle Society (AOFAS) ankle score
2. Visual Analogue Scale score
3. Olerud and Molander score

Patients will be followed up on a routine basis at 3 months and 6 months.

Secondary outcome measures
1. Time of injury to operation
2. Tourniquet time
3. Past medical history
4. Co-morbidities
5. Smoking history
6. Time non-weight bearing post-operation
7. Further surgery
8. Complications

Patients will be followed up on a routine basis at 3 months and 6 months.

Overall study start date
01/06/2008

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. Aged 18 - 65 years, either sex
2. Closed ankle fractures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
146

Key exclusion criteria
1. Children
2. Open wounds
3. Infection
4. Conditions that limit blood supply to the feet
5. Insufficient quality/quantity of bone
6. Poor patient co-operation (alcoholics/intravenous drug users [IVDUs])
7. Diabetics
8. Patients with peripheral nerve conditions
9. Adult unable to give consent

Date of first enrolment
01/06/2008

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
Wirral
United Kingdom
CH49 5PE

Sponsor information

Organisation
Wirral University Teaching Hospital NHS Foundation Trust (UK)

Sponsor details
Arrowe Park Hospital
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Wirral
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CH49 5PE
dr_kenyon@hotmail.com

Sponsor type
Hospital/treatment centre

Website
http://www.whnt.nhs.uk/

ROR
https://ror.org/05cv4zg26

Funder(s)

Funder type
Industry

Funder Name
Inion Ltd (UK) - providing biodegradable plates on a cost-neutral basis

Funder Name
No further funding is required or has been requested.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration