

Outcomes in using biodegradable fixation materials for fractures of the ankle

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Michael Hennessy

Contact details
Wirral University Teaching Hospital NHS Foundation Trust
Arrowe Park Hospital
Arrowe Park Road
Upton
Wirral
United Kingdom
CH49 5PE

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 used to allocate 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

Arrowe Park Road

Upton

Wirral

England

United Kingdom

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