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Bone Biopsy and AntiBiotics study

Submission date	Recruitment status	[X] Prospectively registered
29/05/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/06/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/06/2016	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.futu.co.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Evaluation of the use of bone biopsy to determine antibiotic choice in the management of osteomyelitis of the foot in diabetes: BBAB study

Acronym
BBAB

Study objectives
There is no consensus on the best treatment of osteomyelitis of the foot in diabetes - which is a common and potentially disabling problem. Many centres choose antibiotics with a broad spectrum antibacterial activity, and prescribe them for many weeks or months. While this approach is successful in the majority of cases and can reduce the need for surgery, it is associated with an increased risk of side-effects (including infection with bacteria, such as Clostridium difficile) and encourages the emergence of resistant organisms, such as methicillin resistant Staphylococcus aureus [MRSA]).

Some expert bodies (including the Infectious Diseases Society of America and the International Working Group on the Diabetic Foot of the International Diabetes Federation) recommend that antibiotic choice is targeted on the basis of the results of culture of a specimen of bone obtained under local anaesthetic (bone biopsy), but this is not widely practised. Nevertheless, the use of bone biopsy in this way appeared to improve outcome in one recent study from France, even though this study was flawed by not being randomised and it is possible that other factors contributed to the differences observed.

There is a clear need to establish the benefits and adverse effects of undertaking bone biopsy to guide antibiotic use and that is the purpose of this study. If the apparent benefit of bone biopsy is established, it will have an immediate impact on routine clinical care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire and Rutland REC 2 on the 11th August 2008.

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
Osteomyelitis of the foot in diabetes

Interventions
Patients will be randomised to two groups. The first will have a bone biposy, the culture of which will allow the investigators to target the antibiotics given. The second group will not be biopsied but will have broad spectrum antibiotics given. Both groups will have treatment for at least six weeks with antibiotics, but will be followed up for six months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The incidence at six months of apparent arrest of bone infection without amputation, measured at six months.

Secondary outcome measures
1. Incidence and level of amputation (major or minor)
2. Survival: death related directly or not to infection of the foot
3. Incidence of reactivated or recurrent infection
4. Prevalence of active ulceration (persistent, reactivated or recurrent) at the end of the study
5. Days in hospital (for reasons both related or not to the infection)
6. Complications of bone biopsy
7. Adjustment of chosen antibiotic regimen
8. Duration of antibiotic treatment (intravenous and oral)
9. Infection or colonisation after the initiation of antibiotic treatment of ulcers on either foot (or other clinical infections) with MRSA and/or multiresistant organisms (MDROs): bacteria that are resistant to antibiotics which are typically used in their treatment, e.g., MRSA, vancomycin-resistant enterococci (VRE), or extended-spectrum beta lactamases (ESBL) producing gram-negative bacilli
10. Other superinfections, side-effects and adverse events (including C. difficile diarrhoea) occurring at any stage in the period of follow-up
11. Comparison of the results of baseline microbiological sampling from superficial soft tissue, deep soft tissue and bone
12. Measurement of health outcome, by results of EuroQoL instrument (EQ-5D) at 6 and 12 months after randomisation, and change from baseline

Outcomes will be measured at six months.

Overall study start date
01/09/2008

Completion date
31/08/2010

Eligibility

Key inclusion criteria
1. Type 1 or type 2 diabetes mellitus
2. Aged greater than or equal to 18 years, either sex
3. Previously undiagnosed infection of bone in the foot (excluding disease limited to the tibia and or fibula), which is either definite or strongly suspected on clinical grounds
4. Able and willing to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Critical ischaemia: clinical or other criteria which suggest to the managing clinician that bone biopsy is relatively contraindicated
2. Frailty or disability which would mean that participation in the study might have an adverse effect on patient well being and mood
3. Pregnancy or the possibility of the occurrence of pregnancy during the study period
4. Those who are unwilling or unable to consent

Date of first enrolment
01/09/2008

Date of final enrolment
31/08/2010

Locations

Countries of recruitment
England

France

Germany

Italy

Sweden

United Kingdom

Study participating centre
Foot Ulcer Trials Unit
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Sponsor information

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Nottingham University Hospitals NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Charity

Funder Name

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