

Bone Biopsy and AntiBiotics study

Submission date 29/05/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/06/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/06/2016	Condition category Musculoskeletal Diseases	<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

Study website

<http://www.futu.co.uk/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 biopsy, 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

Nottingham

United Kingdom

NG5 1PB

Sponsor information

Organisation

Nottingham University Hospitals NHS Trust (UK)

Sponsor details

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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