# Bone Biopsy and AntiBiotics study

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

#### Contact name

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#### Contact details

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## Additional identifiers

## Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

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

#### Key secondary outcome(s))

- 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 gramnegative 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.

### 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

## Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

United Kingdom

England

France

Germany

Italy

Sweden

## Study participating centre Foot Ulcer Trials Unit

Nottingham United Kingdom NG5 1PB

## **Sponsor information**

#### Organisation

Nottingham University Hospitals NHS Trust (UK)

#### **ROR**

https://ror.org/05y3qh794

# Funder(s)

## Funder type

Charity

#### Funder Name

Moulton Charitable Foundation (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes