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Comparing swabs and samples in collecting information about infection in diabetic foot ulceration

Submission date
19/09/2011

Recruitment status
No longer recruiting

Registration date
21/09/2011

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims?
Diabetes affects more than 2 percent of the UK population, and is linked with important health problems such as diabetic foot ulcers. About a quarter of people with diabetes will develop a foot ulcer in their lifetime, which can lead to reduced quality of life and higher personal and healthcare costs.
Over half of patients with diabetic foot ulcers will have a wound infection. In order to provide the best treatment it is important to understand the cause of the infection. Because many different bacteria can cause diabetic foot infections, obtaining a wound sample is an important part of providing the best care. A sample from the ulcer is examined in the laboratory to find out which bacteria are causing the infection. This information allows the doctor to prescribe the most suitable antibiotic treatment for the infection.
In current practice, most doctors collect a sample for analysis by wiping the infected wound with a cotton swab. These swabs are widely available, cheap and easy to use. However, some doctors think it is better to take a little piece of the infected ulcer (a curettage sample) in order to identify the harmful bacteria causing the infection.
This study is designed to find out if these two different ways of collecting samples from diabetic foot ulcers give the same answers, or if one is better than the other.

Who can participate?
Patients who
Suffer from diabetes (either type I or type II)
Are 18 and over
Are suspected of having an infected foot ulcer, which will be treated using antibiotics.

What does the study involve?
Once a patient has agreed to take part in the study, their doctor will take a sample from the infected wound using the usual swab technique, but will also take a curettage sample as well. Both samples will be sent to the hospital laboratory for analysis. Once the samples have been taken, the study requires no further patient involvement.

What are the possible benefits and risks of participating?
The risks to patients in this study are minimal. The method used to obtain the curettage sample requires scraping of the ulcer which may lead to some bleeding or pain.
The benefits include better treatment of patients who have an infected foot ulcer and as a consequence better long term health.

Where is the study run from?
Patients will be recruited from both hospital and community clinics. The aim of the study is to recruit 400 patients from 20 different centres.

When is the study starting and how long is it expected to run for?
Recruitment will begin in October 2011 and will run for 15 months until January 2013.

Who is funding the study?
This study is funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA).

Who is the main contact?
Professor Andrea Nelson
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Study website
http://ctru.leeds.ac.uk/codifi

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA: 09/75/01, UKCRN ID: 10440

Study information

Scientific Title
COncordance in DIabetic Foot Infection

Acronym
CODIFI

Study objectives
The aim of this study is to assess the agreement (concordance) between culture results from specimens taken by both surface swabs and by curettage, in patients with a diabetic foot ulcer with suspected infection requiring antibiotic therapy. The study also aims to evaluate whether any changes in bacterial profiles obtained from swabs and tissue samples are clinically relevant by ascertaining from a panel of clinicians whether the reports from swabs or tissue samples would have resulted in a change in clinical management or not.

In addition, via a sub-study, the study aims to assess the concordance between results from specimens taken by conventional culture techniques and by molecular techniques.

More details can be found at http://www.hta.ac.uk/projectdev/2364.asp

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sheffield REC approved on 24th May 2011, Ethics Number: 11/YH/0078

Study design
Multi-centre cross-sectional observational study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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
Diabetic Foot Ulcers (DFU)

Interventions
Patient attending clinic found to have a clinically infected DFU that the clinician feels requires antibiotic treatment. If the person is able to give informed consent they are asked to consent to having both a swab and a tissue specimen taken from the wound. If the patient consents their demographics and characteristics of the wound are recorded. Swab and soft tissue samples are taken and sent to the microbiology laboratory for culture and sensitivity testing.

20 patients will be asked to consent to an additional surface swab sample being taken to allow for duplicate samples to be analysed using genetic techniques. Results of the swab and tissue sample microbiological analysis are reported to clinicians. Local Investigator records the data on the study case report forms (CRFs) for return to the Clinical Trials Reserach Unit (CTRU). Changes to patient antibiotics are recorded at day 7. A panel of clinicians will consider blinded results to judge whether clinical treatment would different.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Presence of likely pathogens (e.g. Staphylococcus aureus, Streptococci, Enterobacter aerogenes, Psuedomonas, Corynebacterium species, Fusobacterium species, Bacteriodes fragilis, Prevotella bivia)
2. Presence of antimicrobial resistance among likely pathogens
3. Number of species detected per specimen

Secondary outcome measures
1. Appropriateness of empirical antibiotic therapy
2. Number and presence of pathogens isolated (conventional plating and molecular techniques)
3. Adverse events
4. Sampling costs

Overall study start date
01/10/2011

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Patient has a diagnosis of diabetes (either type 1 or type 2)
2. Patient has a suspected ulcer infection with or without bone infection, based on clinical signs and symptoms using the Infectious Diseases Society of America / International Working Group on the Diabetic Foot (IDSA / IWGDF IWGDF, 2003) criteria and the judgment of the Investigator
3. The clinical plan is to treat the patient with antibiotics for their infected ulcer
4. Patient is at least 18 years of age at the time of signing the informed consent form
5. Patient is able to understand and willing to give written informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. The clinician deems it inappropriate to take a curette sample or a swab sample for any reason
2. The patient has already been recruited to the study

Date of first enrolment
01/10/2011

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Healthcare
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details

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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) (ref: 09/75/01)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol results	04/01/2013		Yes	No

Results article	31/01/2018	Yes	No