

Predictive factors for foot ulceration in diabetes: a follow-up

Submission date 05/12/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/12/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/09/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetes is a long-term health condition in which a person struggles to control their blood sugar. People with diabetes sometimes have problems with their feet which become serious and this makes getting around harder and life less enjoyable. It might be possible to avoid foot problems by having regular foot checks by doctors, podiatrists or nurses but at the moment it is not clear how useful this is or often it needs to be done. People who learn they might go on to have foot problems expect to be given treatment to stop the problem happening in the first place. But unfortunately the best way to avoid foot problems is not known and more research is needed. But before a large, expensive study called a clinical trial can be done there is a need to study the different ways people with diabetes can have foot care from the NHS. This study will look at how often people with diabetes should have their feet examined by NHS staff, what are the best things for patients and NHS staff to do to stop foot problems from happening, and whether a large clinical trial likely to produce information that is good value for money.

Who can participate?

Diabetic adults who can walk and don't have foot ulcers

What does the study involve?

Routine health information and notes about any foot treatment are collected using electronic patient records. Patients are not required to attend any appointments. The information is then used to work out how often people with diabetes have their feet examined by NHS staff, what the best things for patients and NHS staff to do to stop foot problems from happening are and whether a study looking at this is likely to produce information that is good value for money.

What are the possible benefits and risks of participating?

There are no benefits or risks involved with participating.

Where is the study run from?

Perth Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?

January 2016 to January 2019

Who is funding the study?
National Institute for Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Fay Crawford
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Contact information

Type(s)
Scientific

Contact name
Dr Fay Crawford

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2

Study information

Scientific Title
An evidence-based evaluation of the clinical and cost effectiveness of foot ulcer risk assessment and structured care interventions for people with diabetes

Study objectives
The aim of this study is to quantify the predictive value of clinical risk factors for foot ulceration in people with diabetes who are managed in community settings.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Scotland A Research Ethics Committee, 20/12/2016, ref: 16/SS/0213

Study design

Observational longitudinal cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet**Health condition(s) or problem(s) studied**

Foot ulceration in diabetes

Interventions

Participants of this study are from a previous (unregistered) cohort study, available via <https://www.ncbi.nlm.nih.gov/pubmed/21186178>. This involved among all 3969 patients who were registered with the podiatry service of NHS Tayside, Scotland, UK, 1270 consecutive eligible patients with a diagnosis of DM were first made aware of the study by letter before being invited to participate in the study by a follow-up telephone call and were offered an appointment at a podiatry clinic (based within a primary care medical centre), nearest to their home.

This study is a long term follow up of these patients to ascertain the incidence of foot ulceration after 10 years:

Routinely collected health data and the podiatry notes of participants from the 2011 cohort study who previously gave consent to have the presence of (present/absent) foot ulceration as observed by a health care professional are reviewed using electronic patient records. Patients are not required to attend any appointments.

Intervention Type

Other

Primary outcome measure

Foot ulceration is measured using routinely collected data and patient podiatry notes.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/01/2016

Completion date

01/01/2019

Eligibility

Key inclusion criteria

1. Age 18 years or over
2. Diagnosis of diabetes mellitus
3. Ambulant
4. Free of foot ulceration
5. Able to give written informed consent
6. Having participating in previous cohort study (The risk of foot ulceration in people with diabetes screened in community settings: findings from a cohort study), available to view via <https://www.ncbi.nlm.nih.gov/pubmed/21186178>

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

n = 1192

Key exclusion criteria

1. Unable to give informed consent
2. Non ambulant

Date of first enrolment

01/03/2016

Date of final enrolment

01/09/2016

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre
Perth Royal Infirmary
Podiatry Department
Perth
United Kingdom
PH1 1NX

Sponsor information

Organisation

NHS Fife

Sponsor details

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Sponsor type

Government

ROR

<https://ror.org/05x1ves75>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research, Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication of this long term follow-up study in a peer reviewed journal.

Intention to publish date

01/01/2020

Individual participant data (IPD) sharing plan

The data will be held at the University of Edinburgh (UoE data protection registration number Z6426984), or in a SafeHaven facility.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No