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Clinical Assessment Study of the Foot

Submission date
12/05/2010

Recruitment status
No longer recruiting

Registration date
22/09/2011

Overall study status
Completed

Last Edited
01/03/2016

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Foot problems are common in people aged 50 and over. Doctors often make their diagnosis and decide what should be done on the basis of clinical assessment - that is, what the patient tells them (for example how the problem started and what symptoms they have) and what they find on examining the foot. Occasionally they may also ask for x-rays of the foot.
However, we still do not know what information from the clinical assessment is most important when making the diagnosis, what is likely to happen to foot problems over time, and how best to manage them. This study is designed to answer these questions and provide doctors with this information so that the care of such problems can be improved.

Who can participate?
We are asking everyone aged 50 years and over in four general practices in North Staffordshire to complete a Health Survey Questionnaire. Those who indicate in this questionnaire that they have experienced foot pain in the last year will be invited to attend a research clinic.

What does the study involve?
Participants are asked to attend a research clinic at a local community rheumatology hospital. The clinic includes a clinical assessment of the feet, knees and hands by one of a team of trained research therapists, x–rays of the feet and hands, photographs of the feet, an ultrasound scan of the soles of the feet and a brief questionnaire. All those who respond to the Health Survey Questionnaire and consent to further contact are sent a follow-up postal questionnaire after 3 years. In addition, those participants who attend the research clinic are sent a follow-up postal questionnaire after 18 months.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in this study. This study is an observational study; this means that the researchers do not provide treatments (care is provided as usual by the participants' doctors). It involves questions, examination and x-rays for research purposes only. All the questions, examinations and x-rays in this study are already currently used to assess joint problems in clinics. People with joint problems do occasionally find that even brief physical examination can cause some discomfort, although this is short-lasting and does not indicate any underlying change in their condition. The radiation doses from x-ray examinations of the hands and feet are extremely small in relation to those we receive from natural background radiation. The x-rays in this study are equivalent to a few days of natural background radiation. The

additional lifetime risk of developing cancer for each x-ray examination of the foot and hand is less than 1 in a million. Therefore they are not associated with a significant health risk.

Where is the study run from?
The study is being organised and coordinated from the Arthritis Research UK Primary Care Centre at Keele University. The four participating general practices in North Staffordshire are Furlong Medical Centre, Kingsbridge Medical Practice, Birches Head Medical Centre and Lucie Wedgewood Health Centre. The research clinics will be held at the Haywood Hospital, Burslem, Staffordshire.

When is the study starting and how long is it expected to run for?
The research clinics will run from June 2010 to September 2011. Participants will be followed up at 18 months and at 3 years.

Who is funding the study?
Arthritis Research UK

Who is the main contact?
Dr Michelle Marshall
m.marshall@cphc.keele.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Michelle Marshall

Contact details
Arthritis Research UK Primary Care Centre
Primary Care Sciences
Keele
Newcastle
United Kingdom
ST5 5BG

Type(s)
Scientific

Contact name
Dr Edward Roddy

Contact details
Arthritis Research UK Primary Care Centre
Primary Care Sciences
Keele
Newcastle
United Kingdom
ST5 5BG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8257

Study information

Scientific Title
An observational cohort study to investigate the long-term course of foot pain and foot osteoarthritis in community-dwelling adults aged 50 years and over

Acronym
CAS-F

Study objectives
The overall aim of this study is to investigate the long-term course of foot pain and foot osteoarthritis in community-dwelling adults aged 50 years and over. Participants will be recruited from general practice lists using a Health Survey Questionnaire. Those with foot pain will be invited to attend a research clinic at a local community rheumatology hospital. Assessment for consenting participants will include self-complete questionnaires, digital photography of the feet, functional assessment of the lower limb, clinical assessment of the feet and hands, plain x-rays of the feet and hands, and ultrasound scanning of the plantar fascia. All those responding to the Health Survey and consenting to further contact will be sent a follow up postal questionnaire at 3 years. In addition, those participants who attend the research clinic will be sent a follow up postal questionnaire at 18 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coventry Research Ethics Committee (REC), 19/01/2010, ref: 10/H1210/5

Study design
Single-centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Quality of life

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
Foot pain, foot osteoarthritis

Interventions
The Clinical Assessment Study of the Foot (CASF) is a prospective cohort study which is interested in community-dwelling adults aged 50 years and older with self-reported foot pain. Its main objective is to provide population-based evidence that will indicate the most useful way of assessing older adults with foot pain in primary care. The study will be conducted in five stages:
1. A baseline postal questionnaire sent to all patients aged 50 years and over registered with two separate local general practices
2. A clinical assessment of all those from stage 1 who have had foot pain in the previous year and who consent to further contact and to attending a clinic. The assessment will involve clinical interview, physical examination, digital imaging, ultrasound, measurement of plantar pressure and x-ray.
3. A review of general practice medical records for those who consent
4. A follow-up postal questionnaire at 18 months for all those who attended for a clinical assessment
5. A follow-up postal questionnaire at 3 years for all participants (stage 1 and 2)

Total follow-up length: 36 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Manchester Foot Pain and Disability Index, measured at baseline, 18 months and 3 years

Secondary outcome measures
1. Radiographic foot OA
2. Radiographic hand OA
3. Foot pain persistence
4. Chronic Pain Grade
5. General health (12-iterm short form health survey [SF-12])
6. Current employment status
7. Anxiety and depression (Hospital Anxiety and Depression questionnaire [HAD])
8. Pain location
9. Symptom satisfaction
10. Presence of hand pain and problems
11. Nodes and swelling
12. Participation restriction

13. Secondary care referral
14. Joint replacement surgery

These will be collected at baseline, 18 month follow-up and 3 year follow-up.

Overall study start date
15/05/2010

Completion date
30/09/2013

Eligibility

Key inclusion criteria
Population survey:
1. Registered with one of the four participating local general practices
2. Age 50 years and over at the time of baseline survey, either sex

Invitation to attend for clinical assessment:
1. Responded to baseline Health Survey questionnaire
2. Male and female, lower age limit of 50 years
3. Self-reported foot pain in the previous 12 months
4. Provided written informed consent to further contact

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size for the research clinics : 506; UK Sample Size: 506. Planned sample size for the entire study : 5000

Key exclusion criteria
Vulnerable groups (e.g. significant cognitive impairment, learning difficulties)

Date of first enrolment
15/05/2010

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Arthritis Research UK Primary Care Centre
Newcastle
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University (UK)

Sponsor details
Keele
Newcastle
England
United Kingdom
ST5 5BG

Sponsor type
University/education

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

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK (UK) (ref: MP/18174)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	05/09/2011		Yes	No
Results article	results	01/01/2015		Yes	No
Results article	results	01/01/2015		Yes	No
Results article	results	13/07/2015		Yes	No
Results article	results	01/12/2015		Yes	No
Results article	results	01/02/2016		Yes	No