ISRCTN14121394 https://doi.org/10.1186/ISRCTN14121394

Clinical Assessment Study of the HAnd (CASHA) - 6-year follow-up

Submission date
24/05/2012

Recruitment status
No longer recruiting

Registration date
03/07/2012

Overall study status
Completed

Last Edited
25/08/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The Clinical Assessment Study of the Hand (CAS-HA) started in 2004 and participants have been followed-up every 18 months over 6 years. The study aims to describe the long-term course of hand pain, hand problems and hand osteoarthritis (pain/stiffness of the joints of the hand) in community-dwelling adults aged 50 years and over. Together with a linked study, this study also aims to look at associations between hand and knee osteoarthritis.

Who can participate?
Participants were originally recruited in 2004 and 2005 via questionnaire from the practice lists of two participating local General Practices. All those who indicated on the questionnaire that they experienced hand pain or hand problems in the previous 12 months and who provided consent to further contact were invited to attend for a clinical assessment. Participation at follow-up points has been restricted to those in the original cohort who consent to further contact.

What does the study involve?
The study involves completion of a questionnaire and attendance at a research clinic based within the local hospital for a clinical assessment and x-rays. The questionnaire consists of a Health Questionnaire, which asks about general health and hand problems, and a Regional Pains Survey, which asks about hip, knee and foot pain. The clinical assessment involves an interview, hand examination and assessment, digital imaging of the backs and fronts of both hands, and anthropometric measurement (height and weight). Participants are also assessed using a test of lower limb function. The clinical assessments will be carried out by a team of trained research therapists (occupational therapists and physiotherapists). Plain x-rays are taken of both hands and knees. Participants who do not wish to attend the research assessment clinics will be offered the opportunity to complete postal questionnaires only. Medical records will be reviewed in consenting participants. This is linked to a specific study objective to link osteoarthritis sub-types to GP consultation data in order to explore which hand pain and problems are presented to primary care over the follow-up period of 6 years.

What are the possible benefits and risks of participating?
As this is an observational study, there are no direct benefits for participants in relation to

providing treatment or advice. The x-rays can be reported on by a consultant radiologist should the participant wish this, and the report sent to the GP. The risks from clinical assessment are negligible. Joint pain may be increased during examination, but the participant is fully informed of their rights to request that examinations are not done, and their right to withdraw from the study at any point. The main risk to the participant in this study is from exposure to radiation from the x-rays. The dose has been set by a radiation protection advisor and is relatively low (the equivalent to a few days natural background radiation). The risk from exposure to radiation from x-rays is covered in the Participant Information Sheet, which is sent to the participant prior to attending the research clinic, and is discussed fully during the consent process in the research clinic. Participants are informed that they can still participate in the study without having the x-rays taken.

Where is the study run from?
The Arthritis Research UK Primary Care Centre at Keele University, Staffordshire, England, UK

When is study starting and how long is it expected to run for?
October 2011 to August/September 2012

Who is funding the study?
The current stage of the study (6-year follow-up) is funded by Arthritis Research UK. Earlier stages of the study were funded by the Medical Research Council (MRC).

Who is the main contact?
Dr Helen Myers
h.l.myers@cphc.keele.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr George Peat

Contact details
Primary Care Musculoskeletal Research Centre
Keele University
Keele Road
Staffordshire
Newcastle-under-Lyme
United Kingdom
ST5 5BG
-
g.m.peat@cphc.keele.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11215

Study information

Scientific Title
The course of hand pain, hand problems and hand osteoarthritis in community-dwelling adults aged 50 years and over: the 6-year follow-up of the Clinical Assessment Study of the Hand (CASHA)

Acronym
CASHA

Study objectives
The Clinical Assessment Study of the Hand (CAS-HA) is a longitudinal observational study of community-dwelling older adults aged 50 years and over with self-reported hand pain or hand problems. CAS-HA participants were recruited to the original cohort 6 years ago from the practice lists of two local general practices. Follow-up has been completed using postal questionnaires at 18-month intervals since then. At baseline, 623 people attended a local hospital for a clinical assessment and x-rays. Response rates to the postal follow-ups at 18-month intervals have been excellent. At the end of the last follow-up (54-months) there were 445 participants remaining in the cohort.

The 6-year follow-up study will involve consenting participants completing questionnaires and attending a research clinic at the local hospital for a clinical assessment and x-rays, very similar to the assessment at baseline. It is anticipated that the research clinics will commence in late August / early September 2011 and run for a maximum of ten months. All participants who will be approached for the 6-year follow-up have given consent to taking part in the study and to being contacted again. Of the 445 participants remaining in the cohort for the 6-year follow-up, it is anticipated that 430 will complete the questionnaires, and 325 will also attend for a clinical assessment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands Solihull, 20/07/2011, ref: 11/WM/0196

Study design
Non-randomised observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

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
Musculoskeletal, All Diseases

Interventions
Seven plain x-rays will be taken of the hands and knees as follows: dorsi-palmar views of each hand and wrist, weight-bearing semiflexed posteroanterior (PA) view of both knees, and lateral and skyline views of each knee in a supine position with the knee flexed to 45 degrees.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Australian Canadian Hand Osteoarthritis Index (AUSCAN) measured at baseline

Secondary outcome measures
1. Anxiety and depression (HADS) measured at baseline
2. Current employment status measured at baseline
3. General health (SF-12) measured at baseline
4. Pain location (manikin) measured at baseline
5. Presence of hand pain and problems nodes, swelling, and participation restriction measured at baseline
6. Radiographic hand osteoarthrits (OA) measured at baseline
7. Radiographic knee OA measured at baseline
8. Symptom satisfaction measured at baseline

Overall study start date
26/09/2011

Completion date
27/07/2012

Eligibility

Key inclusion criteria
1. Existing member of the CAS-HA cohort
2. Responded to the 3-year Follow-up Health Questionnaire

3. Provided written informed consent to further contact at 3-year follow-up stage
4. Male & female participants
5. Lower Age Limit 50 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
475

Key exclusion criteria
1. Participants who have died since 3-year follow-up
2. Participants who have become vulnerable (e.g. participants with known new-onset dementia, serious/terminal pathology) since their baseline assessment as judged by the lead GP at each practice
3. Participants who have withdrawn consent to further contact following the 3-year follow-up

We are keen to avoid upsetting or burdening participants and their relatives whose circumstances may have changed. Prior to any contacts being made for 6-year follow-up we will check to ensure that the mailing list contains no participants who have died. This means checking the mailing list at each practice. We are also including a screen of the mailing list by the lead GP at each practice to identify and exclude those participants who have become vulnerable since the screen was last conducted.

Date of first enrolment
26/09/2011

Date of final enrolment
27/07/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Keele University
Newcastle-under-Lyme
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University (UK)

Sponsor details
Keele Road
Staffordshire
Newcastle-under-Lyme
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)

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