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Clinical study of a novel anatomic cuff for forearm crutches

Submission date
07/02/2017

Recruitment status
No longer recruiting

Registration date
14/02/2017

Overall study status
Completed

Last Edited
16/03/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common type of arthritis and affects millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, causing stiffness, pain and a reduction in the range of movement. In some, movement can be limited so severely that they need to use walking aids such as crutches to get around. Using forearm walking aids (crutches that attach at the forearm) often leads to pain in the forearms. Special handles called anatomic handles have been developed to increase the size of the contact area and reduce the pressure, but for many this is ineffective. One third of the load is transferred via the forearm. In contrast to the hand, the ulnar (outer, lower arm bone) is not well protected and this can often lead to compression of the ulna nerve, leading to pain. This study aims to look at the effectiveness of a newly developed anatomic cuff for forearm crutches which aims to protect the ulnar bone and distributing the load towards surrounding muscles and soft tissue.

Who can participate?
Patients with OA who have used forearm crutches on both sides for at least eight weeks.

What does the study involve?
All participants are given the special crutches with the anatomic cuff to use for four weeks. The length of the crutches is adjusted depending on participant height. At the start of the study and then after four weeks, participants complete questionnaires to assess their forearm pain and general helath.

What are the possible benefits and risks of participating?
Participants may benefit from lower pain levels in their forearms than if they used conventional crutches. There are no notable risks involved with participating.

Where is the study run from?
University Hospital Basel (Switzerland)

When is the study starting and how long is it expected to run for?
January 2014 to December 2016

Who is funding the study?
University Hospital Basel (Switzerland)

Who is the main contact?
Professor Thomas Hügle
thomas.huegle@unibasl.ch

Contact information

Type(s)
Public

Contact name
Prof Thomas Hügle

Contact details
University Hospital Basel
Petersgraben 4
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2014/1

Study information

Scientific Title
Prospective clinical evaluation of a novel anatomic cuff for forearm crutches in patients with osteoarthritis

Study objectives
Anatomic cuffs with ulnar protection are less associated with pain and discomfort in long-term users of forearm crutches.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikkomission beider Basel (EKBB) Switzerland, 03/06/2014, ref: E350/12

Study design
Prospective non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
At baseline, all participants receive forearm crutches with an anatomic cuff (Ulnar Pro®, Rebotec, Quakenbrück, Germany) with anatomic hand grip (model soft, Rebotec, Quakenbrück, Germany) to use for four weeks. The length of the crutches are adjusted by the study team to the patients' hand height during stance with the arms positioned at 20 to 30° elbow flexion. Clinical data are collected at baseline and at 4-weeks follow-up using questionnaires.

Intervention Type
Device

Primary outcome measure
Pain along the forearm is measured using a questionnaire based on a unipolar 9-point Likert-scale designed for the purpose of this study at baseline and 4 weeks

Secondary outcome measures
General health is assessed using 36-Item Short Form Survey (SF-36) at baseline and 4 weeks

Overall study start date
01/01/2014

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Suffering from osteoarthritis
2. Have used bilateral forearm crutches for at least 8 weeks prior to the study

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Infections of hands or forearms
2. Amputation
3. Neuropathy (e.g. due to diabetes or syringomyely)
4. Active rheumatic diseases
5. Upper limp injuries

Date of first enrolment
01/03/2014

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Basel
Petersgraben 4
Basel
Switzerland
4045

Sponsor information

Organisation
University Hospital Basel

Sponsor details
Petersgraben 4
Basel

Switzerland
4031

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Basel

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Thomas.huegle@unibas.ch

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/03/2017		Yes	No