# Clinical study of a novel anatomic cuff for forearm crutches

Submission date 07/02/2017	<b>Recruitment status</b> No longer recruiting	
<b>Registration date</b> 14/02/2017	<b>Overall study status</b> Completed	[ [>
Last Edited 16/03/2017	<b>Condition category</b> Musculoskeletal Diseases	Ĺ

] 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 Basel Switzerland 4031

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