

# Clinical study of a novel anatomic cuff for forearm crutches

<b>Submission date</b> 07/02/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/02/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/03/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 health.

### 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@unibas.ch

## Contact information

### Type(s)

Public

### Contact name

Prof Thomas Hügle

### Contact details

University Hospital Basel  
Petersgraben 4  
Basel  
Switzerland  
4031

## Additional identifiers

### Protocol serial number

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)

Ethikkommission beider Basel (EKBB) Switzerland, 03/06/2014, ref: E350/12

### Study design

Prospective non-randomised study

### Primary study design

Interventional

**Study type(s)**

Quality of life

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**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 limb 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

**ROR**

<https://ror.org/04k51q396>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

University Hospital Basel

## Results and Publications

**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](mailto:Thomas.huegle@unibas.ch)

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	14/03/2017		Yes	No