Influence of weightbearing on angular measurement in patients with a hallux valgus deformity and validation of two patient-based questionnaires regarding first ray deformity

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Part one: To quantify the influence of weightbearing on the IMA, HVA and DMAA, measured according the actual gold standard of measurement.Part two: Validation of the Dutch version of the Foot Ankle Outcome Score (FAOS) and the Dutch version of the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON39119

Source
ToetsingOnline

Brief title
Hallux research

Condition

- Joint disorders

Synonym
deformity, hallux valgus, skewed toe

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hallux valgus, non-weightbearing, validation, weightbearing

Outcome measures

Primary outcome

For part one: Influence of weightbearing on IMA, HVA and DMAA in patients with

hallux valgus deformity.

For part two: Validation of the Dutch version of the FAOS and MOXFQ for first

ray deformity.

Secondary outcome

Intra- en interobserver variation for angular measurements of first ray

deformity.

Study description

Background summary

Angular measurement is an important tool for the choice of treatment of hallux valgus deformity. Literature has suggested treatment flow charts for treatment depending of the intermetatarsal (IMA), hallux valgus (HVA) and distal metatarsal articular angles (DMAA). In orthopedic surgery both weightbearing and non-weightbearing foot radiographs are used for measurement of these angles. Little is known about the influence of weightbearing on these specific angles.
Patient outcome and satisfaction questionnaires are increasingly popular in modern medical and surgical follow up. Unfortunately, for forefoot problems no Dutch validated questionnaires is available.

Study objective

Part one: To quantify the influence of weightbearing on the IMA, HVA and DMAA, measured according the actual gold standard of measurement.
Part two: Validation of the Dutch version of the Foot Ankle Outcome Score (FAOS) and the Dutch version of the Manchester-Oxford Foot Questionnaire (MOXFQ) for patients with first ray deformity.

Study design

The study will comprise two parts. Patients will be included according to the GCP principle. For part one, patients will undergo a physical examination and 4 radiographs will be made of each foot. (Antero-Posterior (AP) weightbearing and non-weightbearing & Lateral (LAT) weightbearing and non-weightbearing). Angular measurements will be performed according to the gold standard. For part two, only the patients with first ray deformity will be asked to complete a set of questionnaires, including the Dutch version of the FAOS, MOXFQ, SF-36 and VAS pain and limitation. Two weeks later patients will receive a new set of questionnaires to complete at home and to return to the orthopedic department.

Study burden and risks

Each extremity radiograph (e.g. foot) exposes the patient to <0.01mSv. This means that included patients will receive <0.02mSv extra per foot. This amount is negligible compared to the yearly background radiation at sea level (2-3 mSv). According to the guidelines of the ICRP occasional diagnostic radiography of the extremity is highly unlikely to cause malignancy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patient with uni- or bilateral hallux valgus deformity
- Patient with forefoot disability, other than hallux valgus deformity
- Male or non-pregnant female aged 18-90
- Patients who signed the Ethics Committee approved specific Informed Consent Form

Exclusion criteria

- Earlier foot surgery
- Earlier fracture of any bone of the foot, with exception for phalanx of digitus II-V fracture
- Cerebral palsy
- Rheumatoid arthritis
- Not motivated for inclusion
- Dutch language not mastered
- Pregnant patients

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-02-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	21-12-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	09-07-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	08-11-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL37757.098.11

Study results

Date completed: 01-07-2014

Actual enrolment: 72