“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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A significant difference in angular measurement is expected in weightbearing and non-weightbearing radiographs in patients with hallux valgus deformity.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28015

Bron
Nationaal Trial Register

Verkorte titel
Hallux research

Aandoening

Hallux valgus, hallux rigidus, foot problems, validation, questionnaires, angelar measurements, weightbearing

Ondersteuning

Primaire sponsor: MC Haaglanden
Reinier de Graaf Groep
Overige ondersteuning: Wetenschapsfonds Landsteiner Instituut

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Difference in measured IMA;
2. Difference in measured HVA;
3. Difference in measured DMAA.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

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.

Objective:

Part one: To quantify the influence of weightbearing on the IMA, HVA and DMAA in patients with a hallux valgus deformity, 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, 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 be completed at home and have to be returned to the orthopedic department.

Study population:

Patient referred to the orthopedic outpatient clinic for a foot problem are eligible for inclusion in this study. Primary study population will be patients with a hallux valgus deformity. For part two of the study, patients with first ray deformity in general will be asked to complete two sets of questionnaires.

Intervention:

The intervention is referring the patient for an extra set of two radiographs (AP non-weightbearing and LAT non-weightbearing) per included foot.

Main study parameters/endpoints:

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.

Nature and extent of the burden and risks associated with participation benefit and group relatedness:

Each extremity radiograph (e.g. foot) exposes the patient to <0.01mSv. This means that included patients will receive <0.02mSv extra per included 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.

Doel van het onderzoek

A significant difference in angular measurement is expected in weightbearing and non-

weightbearing radiographs in patients with hallux valgus deformity.

Onderzoeksopzet

Twice with a window of at least 2 weeks.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient with uni- or bilateral hallux valgus deformity;

2. Patient with forefoot disability, other than hallux valgus deformity;

3. Male or non-pregnant female aged 18-90;

4. Patients who signed the Ethics Committee approved specific Informed Consent Form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Earlier foot surgery;

2. Earlier fracture any bone of the foot, with exception for phalanx of digitus II-V fracture;

3. Cerebral palsy;

4. Rheumatoid arthritis;

5. Not motivated for inclusion;

6. Pregnant patients.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2012
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	07-08-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3415
NTR-old	NTR3565
Ander register	METC MC Haaglanden : 11-108
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A