

Can we reduce the Hallux Valgus Angle when using "Step Forward Orthotics" insoles in people with mild to moderate Hallux valgus? A pilot study.

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We will investigate whether wearing the insoles can cause a reduction in the hallux valgus angle and the angle intermetatarsaal angle. Furthermore, we investigate the possible decrease in pain and improvement in functional score.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON46074

Source

ToetsingOnline

Brief title

Hallux Valgus Orthotics

Condition

- Bone disorders (excl congenital and fractures)

Synonym

crooked big toe, hallux valgus

Research involving

Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: Onderzoeksrekening Orthopedie

Intervention

Keyword: hallux valgus, orthotics, reduction

Outcome measures

Primary outcome

The main outcome of the magnitude of the hallux valgus angle.

Secondary outcome

1. Can wearing "Step Forward Orthotics" orthotics for one year in people with mild and moderate Hallux valgus provide a reduction in pain?
2. If the participants who have been using the insoles for one year can choose again would they choose the insole of a surgery?
3. Are the function scores and quality of life improved with the use of these insoles (measured over the time)?
4. Does the intermetatarsal angle (IMA) become smaller after one year?
5. Are the measurements of the hallux valgus angle (HV) on the x-rays similar to the blueprint results and digital photos? The blueprint results and digital photos are used in the office. We want to know whether they are reliable enough to be used in the future to measure the HV.
6. What is the minimal Important change?
7. What is the "smallest detectable change (SDC) in the measurement of the HV and IMA, ie what is the measurement error?

Study description

Background summary

Hallux valgus is a common foot problem, which is often accompanied by pain at the art. 1st metatarsophalangeal. This can lead to limitations in activities and participation and an increased risk of falling. When the Hallux Valgus is combined with pain and limitations, this often leads to surgery. Recently, there is some evidence that wearing a particular insole ("Step Forward Orthotics") could reduce the hallux valgus angle.

Study objective

We will investigate whether wearing the insoles can cause a reduction in the hallux valgus angle and the angle intermetatarsal angle. Furthermore, we investigate the possible decrease in pain and improvement in functional score.

Study design

prospective cohort study

Study burden and risks

During this study, the test subjects are exposed to a low dose of X-rays. Two x-rays of the feet are made. All data is coded. Participants will receive the normal treatment with the additional X-rays and an online questionnaire. When wearing the insoles your feet can feel sore and tired at the beginning. A possible benefit is the decrease of Hallux valgus angle by using these insoles.

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

- Patienten die zich aanmelden voor een Step Forward Orthotics steunzool
- Age between 18-70 years.
- Hallux Valgus (HV) has an angle of a mild-to-moderate HV $<25^\circ$ (radiographic angle between the longitudinal axis of MT 1 and the longitudinal axis of the base phalanx)
- The minimal pain score (NRS) is scored on a 2 last week.

Exclusion criteria

- Patients who sign up for a Step Forward Orthotics insole
- HV rigidus (total range of motion (dorsiflexion + plantar) of less than 50°)
- Diabetes mellitus,
- HV operation in history
- neuropathy
- poliomyelitis
- rheumatoid arthritis

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 01-11-2016
Enrollment: 21
Type: Actual

Medical products/devices used

Generic name: Insoles
Registration: Yes - CE intended use

Ethics review

Approved WMO
Date: 19-09-2016
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO
Date: 31-10-2016
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 05-01-2017
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 22-06-2017

Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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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	NL57888.098.16