Using in-shoe plantar pressure measurements to optimize inlays at patients with rheumatoid arthritis and footcomplaints: pilotstudy

Published: 21-08-2012
Last updated: 26-04-2024

Goal of this project is to evaluate an innovative protocol for optimizing inlays based on insole plantar pressure measurements in patients with RA. The protocol will be evaluated on the following aspects: (i) the process of optimizing inlays based…

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

Summary

ID

NL-OMON37106

Source
ToetsingOnline

Brief title
Optimizing inlays in RA patients by using in-shoe pressure measurements.

Condition

- Joint disorders

Synonym
rheumatism, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reade, afdeling O&O

Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: inlays, in-shoe plantar pressure measurement, podiatry, rheumatoid arthritis

Outcome measures

Primary outcome

Primary outcome measurements in this study are pressure time integral (PTI),

pain and functioning.

Measuring Instruments

* Insole plantar pressure measurement: Peak Pressure (PP) and Pressure Time

Integral (PTI)

* Mannequin (likert scale)

* Foot Impact Scale (FIS-RA)

* Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

* Foot Function Index (FFI)

* Numeric Rating Scale (0-10)

* 10-meter getimede looptest

* Global Rating of Change

* Disease Activity Score 44 (DAS44)

Secondary outcome

Not applicable

Study description

Background summary

Foot complaints are common in patients with arthritis. Approximately 90% of patients with rheumatoid arthritis (RA) develop painfull feet or ankles during the course of their disease. Data collected in a large RA cohort at Reade showed that approximately 70% of adult patients had inflammation in one or more joints of the forefoot at disease onset. After (drug) treatment this rate dropped to 40%. The percentage of patients with joint damage on radiographs in forefoot joints increased of approximately 20% at disease onset to 60% after 8 years of disease duration. Foot complaints lead to pain in activities, such as standing, walking and climbing the stairs. Approximately 40% of the patients experienced walking problems during the first 8 years of the disease.
Treatment of foot complaints consist of surgical intervention, treatment with medication, and/or conservative treatment. Conservative treatment includes inlays which are worn in the shoes. The inlays are made by a podiatrist, on referral from a rehabilitation physician or rheumatologist. The purpose of these inlays is reduction of the pressure under the feet, since high plantar foot pressure is associated with joint damage and pain. Determining high plantar foot pressure happens mostly through inspection and making a blueprint. Research of Guldemond et al in patients with forefoot complaints shows that this method leads to high variability in locating high plantar foot pressure and is unreliable. The recommendation of this study is to perform plantar pressure measurements in the shoe to locate high plantar pressure correctly. Clinical practice also shows that the current approach is not optimal; patients with RA often have to return several times to the podiatrist because the inlays have not the desired effect on pain reduction.
For this study insole plantar pressure measurements will be used as a diagnostic tool for optimizing inlays. If insole plantar pressure measurements with inlays demonstrates that the plantar pressure has changed insufficiently, the inlays will be adjusted. Multiple rounds of insole plantar pressure measurements and inlay adjustments can take place to optimize the inlays. We expect that this method of insole plantar pressure measurements and inlays adjustments will lead to optimal inlays after one treatment session and therefore to faster and more pain reduction than usual care. A similar method of inlay adjustments based on insole plantar pressure measurements is already applied in patients with diabetes mellitus (Bus et al). In patients with diabetes mellitus insole plantar pressure measurements have been used to optimize orthopedic shoes to prevent recurrent ulcerations.

Guldemond, N. A., Leffers, P., Nieman, F. H., Sanders, A. P., Schaper, N. C., and Walenkamp, G. H.Testing the proficiency to distinguish locations with elevated plantar pressure within and between professional groups of foot therapists.2006;7:93-

Bus, S. A., Haspels, R., and Busch-Westbroek, T. E.Evaluation and optimization of therapeutic footwear for neuropathic diabetic foot patients using in-shoe

plantar pressure analysis.2011;34:1595-1600.

Study objective

Goal of this project is to evaluate an innovative protocol for optimizing inlays based on insole plantar pressure measurements in patients with RA. The protocol will be evaluated on the following aspects: (i) the process of optimizing inlays based on insole plantair pressure measurements (feasibility) and (ii) the result of the inlays on plantar foot pressure, pain and physical functioning.

Study design

This study will be performed as a pilot study. Forty RA patients will be treated according to the innovative protocol. The treatment will be carried out in a treatment session and a control session after 2 months. The treatment session consists of a diagnostic phase and an intervention phase. During the intervention phase inlays will be made and, if necessary, optimized through multiple rounds of insole plantar pressure measurements and inlay-adjustments, with a maximum of 3 rounds.
In the control session insole plantar pressure measurements will be repeated. If necesarry, the insoles will be adjusted in the context of usual podiatry care.

Study burden and risks

The podiatry treatment of this project is equal to usual podiatric care in Reade. The burden for patients is minimized wherever possible and differs on some points from usual podiatric care.

Additional burden for the patient:
-the intake will be up to 45 minutes longer because of extra insole plantar pressure measurments and possible insole adjustments.
-At the end of the treatment an interview will take place with 10 of the 40 participating patients. This interview will take place adjacent to the appoinment with the podiatrist and wil take a maximum of 45 minutes.
- At the end of the treatment a comprehensive satisfaction questionnaire will be assessed in all patients.

Advantages for the patient:
-Treatment according to the innovative protocol is expected to be more time efficient and more effective. We expect that the patient is provided with optimal inlays after the first treatment session.

Risk
Since the podiatry treatment of this project is equal to usual podiatric care,

there are no additional risks related to this study.

Contacts

Public
Selecteer

Dr. Jan van Breemenstraat 2
Amsterdam 1056 AB
NL
Scientific
Selecteer

Dr. Jan van Breemenstraat 2
Amsterdam 1056 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-RA diagnosed by a rheumatologist according to the revised criteria of the American Rheumatism Association
-Referred to podiatry because of foot problems
-Indication for inlays
-* 18 years

Exclusion criteria

-Another medical condition that underlies the foot complaints
-Not able to walk independently, not even when using crutches or orthotic facilities
-Can't fill out questionnaires because of language or cognitive difficulties
-Refusal to sign the informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	21-08-2012
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL41146.048.12