The effect of joint mobility on plantar pressures and walking capacity in diabetic patients with and without previous foot ulceration.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON31101

Source ToetsingOnline

Brief title

Joint mobility and plantar pressure in diabetic patients.

Condition

• Diabetic complications

Synonym diabetes mellitus, diabetic foot

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diabetic foot, foot pressure, joint mobility, walking capacity

Outcome measures

Primary outcome

 The relationship between joint mobility of the foot, ankle and hip and plantar foot pressure in diabetic patients with and without a previous foot ulcer.

Secondary outcome

2) The relationship between joint mobility of the foot, ankle and hip and

walking capacity in diabetic patients with and without a previous foot ulcer.

3) The relationship between (passive) joint mobility of the foot, ankle and hip

and dynamic joint mobility in these joints during walking in diabetic patients

with and without a previous foot ulcer.

Study description

Background summary

The prevalence of diabetes mellitus is dramatically high and is further increasing due to the aging of the population and changes in lifestyle. Diabetic neuropathy is the most frequent complication of diabetes. It presents a group of clinical syndromes, among which the most frequent is distal, mainly sensory polyneuropathy. Diabetic peripheral neuropathy causes changes in foot structure, affecting foot function and subsequently leading to increased plantar foot pressure, which is a predictive risk factor for the development of diabetic foot ulceration. Loss of protective sensation, development of foot deformities, limited joint mobility and reduced plantar soft tissue thickness all contribute to an increased risk of foot ulceration. It is estimated that the lifetime risk of a foot ulcer for any diabetic patient is approximately 15%. Foot ulceration is a major cause of disability and is one of the most common causes for hospital admission among diabetic patients.

Limited joint mobility (LJM) is a common manifestation of diabetes. The condition is usually most prominent in the hands but also affects the joints of the ankle and foot in diabetic patients and may predispose to increased plantar pressure and foot ulceration, and may lead to difficulties with walking. Although LIM of the foot has been shown to be related to increased plantar pressure and to foot ulceration, the role of joint mobility in the development of foot ulceration is still not completely understood. Additionally, mobility of more proximal joints such as the knee and hips or the role of LJM on walking capacity has not been investigated before. It is hypothesized that reduced joint mobility also exists at more proximal joints, and that this also could contribute to increased plantar foot pressures. Furthermore, walking capacity in patients with peripheral neuropathy may be compromised due to reduced stability and LJM; however this has not been addressed in the literature before. Reduced walking ability may lead to a reduced walking activity and this is an undesirable consequence as the benefits of regular walking are well established and walking has been entitled as the best medicine for diabetes. More knowledge about the effect of limited joint mobility on foot pressure and walking capacity are necessary in order to be able to design future clinical interventions and intervention studies aiming to improve physical activity in daily life in diabetic neuropathic patients.

Study objective

The objective of this project is to assess joint mobility of the foot, knee and hip to investigate in more detail the relationship between joint mobility of the lower extremity, plantar pressures and walking capacity in diabetic patients with and without a history of foot ulceration.

Study design

A cross-sectional observational study.

Study burden and risks

Patients will attend the department of rehabilitation of the AMC once. During this visit a short clinical examination will take place, a 2 minute walking test and gait analyis will be performed, and foot pressures will be assessed. The workload of the different tests is possible if enough resting breaks are taken between the different tests.

Contacts

Public Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

The inclusion criteria are 1) diagnosis of diabetes mellitus type 1 or 2; 2) ability to walk 2 minutes.

Exclusion criteria

Exclusion criteria are: 1) osteomyelitis, 2) clinically infected foot ulcer, 3) walking ability limited by co-morbidities e.g. intermittent claudication, unstable angina, hemiplegia, arthroplasties, CPOD tolerance, sciatica.

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	60
Туре:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

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

ССМО

ID NL16391.018.07