

The prevalence of impairments and limitations in activities and participation of leprosy patients in the Netherlands, and the evaluation of biomechanical risk factors for foot ulceration in leprosy patients with peripheral neuropathy.

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The objectives of the study are:1) To evaluate the prevalence of secondary impairments and to evaluate the limitations in activities related to severity of impairments and restrictions in participation in leprosy patients in the Netherlands.2) To...

Ethical review	Approved WMO
Status	Pending
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON30197

Source

ToetsingOnline

Brief title

Biomechanical risk factors for foot ulceration in leprosy patients

Condition

- Peripheral neuropathies

Synonym

Hansen's disease, Leprosy

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: De Nederlandse Leprastichting/Netherlands Leprosy Relief

Intervention

Keyword: Biomechanics, Foot, Impairments, Leprosy

Outcome measures

Primary outcome

First part of the study: Survey

1. Impairments questionnaire
2. Impact on participation and autonomy questionnaire (IPA)
3. WHO-DAS II (impairments)

Second part of the study: subgroup analysis

1. Walking capacity (6 minute walking test)
2. Barefoot plantar footpressure
3. History of foot ulceration

Secondary outcome

Second part of the study: subgroup analysis

1. Clinical assessment to confirm neuropathic foot and inclusion/exclusion criteria
2. Demographics
3. CIRS questionnaire (co morbidity)
4. Foot examination (mobility, deformities)

5. In-shoe plantar pressure

6. 7 day walking activity

7. Footwear use

Study description

Background summary

Leprosy results in autonomic, sensory and motor neuropathy, which can lead to the development of secondary impairments such as skin lesions (ulcers, blisters and burns), hand and foot deformities (clawing of toes and fingers, absorption of digits and neuro-osteoarthropathy) and eye lesions. As a result of impairments, many people experience limitation of activities and experience restrictions in their participation in society.

Although multi-drug therapy has reduced the number of leprosy patients developing impairments, many patients both on treatment and released from (drug) treatment have and often continue to have impairments of the foot, and are still walking around on neuropathic ulcerated feet. Plantar ulcers are well recognized as a major cause of disability in leprosy. Foot ulcers can lead to complications such as cellulitis and osteomyelitis and subsequently increase the risk of amputation. However, this is preventable through the use of appropriate footwear and preventative foot management. Much time and money is spent on foot care that could have been prevented by early detection and more effective care. To date the effect of leprosy on limitations of activities in westernized countries has been a neglected (research) area. Furthermore, research into the role of foot biomechanics and the risk factors of increased plantar pressure in the neuropathic foot in leprosy patients has been often observational and limited. Additionally, the effect of footwear on plantar pressure and the effect of daily activity on accumulative stress on the foot has received no or very limited attention to date.

Study objective

The objectives of the study are:

- 1) To evaluate the prevalence of secondary impairments and to evaluate the limitations in activities related to severity of impairments and restrictions in participation in leprosy patients in the Netherlands.
- 2) To explore the association between severity of impairments, walking capacity, walking activity and limitations in activities in leprosy patients with neuropathic foot impairments.
- 3) To identify which impairments are determinants of increased plantar pressure in leprosy patients with foot impairments.

4) To identify which footpressure parameters are the best determinants of foot ulceration.

Study design

A cross-sectional questionnaire survey and in a subgroup a detailed observational study

Study burden and risks

The study participants with a neuropathic foot as a consequence of leprosy will visit the department of rehabilitation AMC twice. During the first visit they will perform a walking test and a clinical examination is performed and questions about health are asked. Additionally the patient is given a step activity monitor and is asked to wear this for 7 consecutive days (until the 2nd visit). During the second visit the footpressure assessments will be done and the step activity monitor is given back to the researcher.

There are no risks attached to the performance of the walking tests and the foot pressure measurements. Between the walking test sufficient rest periods will be given to the participants.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9, Postbus 22660
1100 DD Amsterdam
Nederland

Scientific

Academisch Medisch Centrum

Meibergdreef 9, Postbus 22660
1100 DD Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- 1) Diagnosis of Leprosy
- 2) Having attended the Tropical Dermatology outpatient Clinic at the AMC within the last 15 years
- 3) Age >18 yrs; Additional in criteria for detailed foot analysis

Inclusion criteria:

- 1) Peripheral neuropathy (for patients attending for detailed foot analysis)

Exclusion criteria

1. Diabetes mellitus
2. Co-morbid disease with significant limited walking ability, including COPD, significant cardiovascular disease, vaso-occlusive diseases, hemiplegia, arthroplasty and sciatica
3. Osteomyelitis or infection of the neuropathic foot (ulcer)
4. Acute neuro-osteoarthropathy
5. Inability to walk (walking aids are permitted as long as foot pressure measurements can be assessed)

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-09-2006

Enrollment: 300
Type: 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	ID
CCMO	NL12920.018.06