Limited Joint Mobility in upper extremity in type 2 diabetes patients in general practice: A cross sectional study

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

Summary

ID

NL-OMON46415

Source
ToetsingOnline

Brief title
Limited joint mobility in type 2 diabetes

Condition

- Diabetic complications
- Musculoskeletal and connective tissue disorders NEC

Synonym
Limited Joint Mobility; musculoskeletal complaints

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,De externe PhD

kandidaat;mevr L. Alabdali (arts);is in dienst bij het ministerie van Hoger Onderwijs in Saoedie Arabië en heeft een beurs voor dit onderzoek

Intervention

Keyword: Cross-sectional study, Diabetes, Limited Joint Mobility, Upper extremity

Outcome measures

Primary outcome

1. The prevalence of upper extremity Limited Joint Mobility in patients with

type 2 diabetes;

2. The prevalence of specific shoulder disorders in type 2 diabetes patients

with shoulder pain;

3. The presence of muscle denervation, as a sign of diabetic neuropathy, in

type 2 diabetes patients with shoulder pain.

Secondary outcome

The association between muscle denervation and shoulder disorders in patients

with and without type 2 diabetes

Study description

Background summary

Diabetes is common in the Netherlands, and also shoulder and hand disorders are frequently seen in Dutch general practice. Despite the fact that several international studies concluded that examination of the hand and shoulder should be included in diabetic patients* periodic checks, screening for limited joint mobility (LJM) is not incorporated in the guidelines. Given the relationship between the duration of hyperglycaemia and LJM, the question arises whether LJM is also prevalent in the Dutch diabetes population. If LJM is prevalent, early diagnosis and treatment can reduce pain and functional limitations, allowing for a better control of normal daily activities, self-management and quality of life. Furthermore, the exact pathophysiology of shoulder disorders in diabetes patients remains uncertain, but there is

evidence that the shoulder can be affected through two pathophysiological pathways: connective tissue damage and neuropathy. New, in-depth knowledge is needed in order to prevent the development of chronic shoulder pain.

Study objective

The objectives of our study are
1) to estimate the prevalence of LJM in patients with diabetes type 2 in The Netherlands, with a special focus on the shoulder.
2) to better understand the role of diabetic neuropathy in the development of shoulder disorders.

Study design

Observational cross sectional study composed of two phases; the first phase is descriptive and the second phase is analytic.

Study burden and risks

Filling in the questionnaire in phase 1 takes approximately 10-15 minutes. No risks are associated.
In phase 2 the participants spend 30-60 minutes in the research centre (Meditta Medical Centre); the participants undergo a physical examination and ultrasound scanning of the shoulder. All these test are non-invasive and no risks are known. Healthy participants will be examined at their department; this takes 15 minutes.

Contacts

Public
Universiteit Maastricht

Debyeplein 1
Maastricht 6229 HA
NL
Scientific
Universiteit Maastricht

Debyeplein 1
Maastricht 6229 HA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Phase 1
- Type 2 diabetes
- men and women aged 30-70 year
Phase 2
- Subjects with shoulder pain for at least four weeks
- Matched patients (non-diabetic) with shoulder pain

Exclusion criteria

Inability to fill out the questionnaire or sign the informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-01-2018
Enrollment:	2140
Type:	Actual

Ethics review

Approved WMO Date:	23-11-2017
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	25-04-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-08-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL63328.096.17