Limited joint mobility in type 2 diabetes.

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25355

Source
Nationaal Trial Register

Health condition

Research has shown that diabetic patients have an increased risk for developing limited joint mobility (LJM). In this study LJM is used as an umbrella term for several musculoskeletal disorders such as adhesive capsulitis, carpal tunnel syndrome, dupuytren contracture and trigger finger. 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

Sponsors and support

Primary sponsor: Dept. of Family Medicine, Maastricht University
Source(s) of monetary or material Support: no funding

Intervention

Outcome measures

Primary outcome

The three primary outcomes of this study are the following:

1. The prevalence of upper extremity LJM in patients with T2DM;

2. The prevalence of specific shoulder disorders in T2DM patients with shoulder pain;

3. The presence of muscle denervation, as a sign of diabetic neuropathy, in T2DM patients with shoulder pain.

Secondary outcome

The association between muscle denervation and shoulder disorders in patients with and without T2DM.

Study description

Background summary

Background:

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.

Objectives:

Primary objectives:

1. Estimate the prevalence of upper extremity LJM in patients with T2DM;

2. Estimate the prevalence of specific shoulder disorders in T2DM patients with shoulder pain;

3. Investigate whether muscle denervation, as a sign of diabetic neuropathy, is present in T2DM patients with shoulder pain.

Secondary objective:

Investigate whether muscle denervation is associated with rotator cuff disorders and adhesive capsulitis in patients with and without T2DM.

Research questions:

Phase 1:

- What is the prevalence of upper limb LJM in T2DM patients in general practice?

Phase 2:

1- What is the prevalence of specific shoulder disorders in T2DMs patients with shoulder pain?

2-Do T2DM patients with shoulder pain have signs of muscle denervation suggesting neuropathy?

Study design:

Cross sectional study.

Population:

T2DM patients aged between 30 and 70 years will be recruited for phase 1 during their periodic check-up by diabetes nurses. Those patients from phase 1 who suffer from shoulder pain will be invited to participate in phase 2. Additionally, non-diabetes patients with shoulder pain referred to the Meditta Medical Center by GPs for ultrasound imaging (US) will be recruited to serve as control subjects.

Intervention:

Phase one: A patients questionnaire that enquires musculoskeletal pain of the upper extremity, including questions about complaints and disorders.

Phase two: The following diagnostic examinations will be carried out: a regular shoulder ultrasound, a physical examination of the shoulder, and a Qualitative Muscle Ultrasound of the shoulder for grayscale analysis.

Recruiting countries:

This study will be conducted in The Netherlands.

Study objective

We hypothesize that patients with type 2 diabetes mellitus (T2DM) in the Netherlands have a lower prevalence of limited joint mobility compared to the literature (phase one). Diabetes patients with shoulder pain have shoulder muscle denervation, as a sign of diabetes neuropathy (phase two).

Study design

The measurements will be carried out from March 2018 to July 2018.

Intervention

Phase one: Nurse practitioners, employed by the diabetes care group Meditta in The Netherlands, approach T2DM patients during the regular diabetes check up to fill in a questionnaire. These nurses are trained in providing the information of the study. Interested patients will receive an envelope containing the following documents: patient information letter, informed consent , patient questionnaire, a separate invitation letter for phase 2 attached to the questionnaire, and a return envelope. Additionally, the diabetes nurse fills in a short case report form containing last reading of HbA1C, current BMI and year of diabetes diagnosis. The patients' questionnaire will enquire about sex and age, and musculoskeletal pain of the upper extremity, including questions about complaints and disorders.

Phase two: Type 2 diabetes patients who indicate in phase 1 to suffer from shoulder pain and have interest in phase 2 will be invited for diagnostic examinations: a physical exam of the shoulder and a neurological exam of the feet, a regular shoulder ultrasound performed by a radiologist, and a Qualitative Muscle Ultrasound of the shoulder for grayscale analysis, which will be performed by a trained medical doctor of our research team.

Contacts

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Eligibility criteria

Inclusion criteria

Phase 1: Patients with type 2 diabetes, men and women aged between 30 and 70 years.

Phase 2: Patients from phase one with shoulder pain for at least four weeks. For matched control subjects, non-diabetes patients with unilateral shoulder pain will be included.

Exclusion criteria

Patients who meet any of the following criteria will be excluded from participation

1- Inability to complete a questionnaire independently

2- Unable to give informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-03-2018
Enrollment:	1900
Type:	Unknown

Ethics review

Positive opinion

Date:	21-03-2018
Application type:	First submission

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
NTR-new	NL6909
NTR-old	NTR7104
Other	METC Zuyderland-Zuyd : 17-T-138

Study results