Hand function of working patients with osteoarthritis of the hands

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Primary Objective: Compare grip strength of working patients with OAH with healthy workers. Secondary Objective(s): To compare the results of the supplementary tests of

working patients with OAH with healthy workers. To describe the possible...

Ethical review Approved WMO

Status Recruitment stopped

Health condition type Joint disorders

Study type Observational non invasive

Summary

ID

NL-OMON39355

Source

ToetsingOnline

Brief title

Functional Capacity of osteoarthritis of the hands

Condition

Joint disorders

Synonym

degenerative joint disease

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: functional capacity, hands, osteoarthritis

Outcome measures

Primary outcome

Main study parameter/endpoint

Grip Strength

Secondary outcome

1. Secondary study parameters/endpoints

Perdue pegboard: fingertip dexterity

Complete Minnesota dexterity test: gross movement coordination

Pinch test: finger strength

The overhead lift

The overhead work test

Repetitive reaching

2. Other study parameters

Sociodemographics

FIHOA (dutch version)

QuickDASH-DLV

Study description

Background summary

The population in developed countries is ageing, causing an increase in health care costs. Prolonged working of the ageing population is one of the elements

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that seems necessary to manage these costs. However, with age, some health issues interfere with this seemingly logical evolution. Osteoarthritis (OA) for example, a disease with a high prevalence, increases with age. OA is the most common form of arthritis. In 2006 1,2 million people in the Netherlands suffer from Osteoarthritis. According to the *Nationaal Kompas Volksgezondheid*, the prevalence of osteoarthritis in the Netherlands has risen by 50% from 1990 to 2007. From 2007 to 2040 it is expected that this number will increase by another 50%.

OA is one of the leading causes for loss of work and disability. In populations of white North Americans and Northern Europeans, about one-third of adults aged 25-74 years have features of radiographic OA involving at least one peripheral joint group: the most common sites are the hands, followed by the feet, knees and hips. Osteoarthritis of the hands (OAH) has an important impact on quality of life in terms of pain, reduced joint mobility and grip strength, activity limitations and participation. Not much is known about the effects of OAH on work participation. To know what the impact of OAH on work participation is, it is essential to know what patients with OAH are capable of doing; what their functional capacity (FC) is. The FC of patients with OA of the knees and hips is worse compared to healthy ageing workers. However, little is known about the FC of patients with OAH that are working. Knowledge on the functionality of working patients with OAH is needed to be able to develop (vocational) rehabilitation programs that meet the need of these patients. The aim of this study is therefore to compare the Upper Limb FC (ULFC) of working patients with OAH with the ULFC of healthy workers. We expect that this study will increase the knowledge about the ULFC of working patients with OAH, which should ultimately lead to improved and sustained work participation of patients with OAH.

Study objective

Primary Objective:

Compare grip strength of working patients with OAH with healthy workers.

Secondary Objective(s):

To compare the results of the supplementary tests of working patients with OAH with healthy workers.

To describe the possible subjective limitations of working patients with OAH, with two questionnaires.

Study design

Forty working patients with OAH that meet the inclusion criteria will be included. Patients are recruited from the UMCG, MCL and OZG. Sociodemographic and clinical data like age, gender, ethnicity, height, weight, primary occupation and *activities involving intensive us of the hands (e.g. sports, gardening, playing specific musical instruments)*, will be collected. After

inclusion the patients with OAH will be classified according to the ACR criteria, Kellgren and Lawrence radiologic classification and the severity level of pain in the previous month on a Visual Analogue Scale (VAS). The included patients will perform functional tests measuring the ULFC and will fill out two questionnaires.

The Tests are

- 1. Grip test: hand strength
- 2. Perdue pegboard: fingertip dexterity
- 3. Complete Minnesota dexterity test: gross movement coordination
- 4. Pinch test: finger strength
- 5. The overhead lift
- 6. The overhead work test
- 7. Repetitive reaching

The questionnaires are:

- FIHOA (Functional Index for Hand Osteoarthritis). Dutch version translated by Wittoek et al based on the original French FIHOA. Wittoek demonstrated excellent psychometric properties (test-retest reliability, construct validity and internal consistency).
- QuickDASH-DLV (Quick Disabilities of Arm, Shoulder and Hand, Dutch Language Version). This questionnaire includes an optional module about work. The QuickDASH has excellent psychometric properties shown by Beaton et al, Gummesson et al and Veehof et al.

Firstly the obtained grip strength will be compared between working patients with OAH and healthy workers. Secondly the remaining tests will be compared between working patients with OAH and healthy workers.

The data of the healthy workers will be extracted out of an existing database(METC protocol 2005/198: Prof. Dr. M.F. Reneman was Principal Investigator of this study). The used end points and way of obtaining them are the same for both studies (2005/198 and current study).

It is our intention to match the whole group of working patients with OAH with the whole group of healthy workers according to known or expected interfering variables (age, gender and work load). As in study 2005/198 the work load of test subjects will be determined according to the DOT (Dictionary of Occupational Titles: http://www.occupationalinfo.org) . The work load is subdivided in *Sedentary*, *Light*, *Medium*, *Heavy* en *Very Heavy*. In terms of percentage the number of test subjects in each of the DOT subdivisions will be made equal in both groups.

Study burden and risks

This is a cross sectional study that studies the effect of OAH on functionality. Extended experience with FCE (functional capacity evaluation) in previous research and clinical care shows limited burden and risks for participants.

There is a temporary risk of *overuse* of muscles and tendons (as with healthy people) causing muscle-soreness.

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According to the international commission on radiological protection (ICRP) the estimated risk per subject for 1 x-ray of the limbs and/or joints is categorized as I: negligable risk of radiogenic cancer(<0.01mSv). In comparison, according to the * Rijks Instituut Voor Milieuhygiëne (RIVM)*, the annual radiation dose in the Netherlands is 2.4 mSv. The physical discomfort during the radiological investigation is minimal. The subject will be asked to sit still for the radiological investigations for 1 time less than 1 minute.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- a. Working (defined as >8hrs/week for the last year).
- b. Diagnosed with primary OAH based on a Kellgren Lawrence rating >2.
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c. Patient has signed informed consent and is able to perform the 7 tests and to fill out the questionnaires.

Exclusion criteria

- a. Incapacitated subject.
- b. Trauma of the upper limbs interfering with research aims.
- c. Operative procedures of the upper limbs interfering with research aims.
- d. Co-morbidites of the upper limbs influencing hand-function interfering with research aims.
- e. Relevant co-morbidities unrelated to the upper limbs, but influencing the execution of the ULFC(upper limb functional capacity) tests (for example cardiovascular diseases and psychiatric disorders).

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 18-10-2012

Enrollment: 40

Type: Actual

Ethics review

Approved WMO

Date: 27-04-2012

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 12-06-2013

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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 NL38340.042.11