Evaluation and development of clinical outcome measures and instruments in hand osteoarthritis from the perspective of patients

Published: 16-07-2007
Last updated: 08-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31224

Source
ToetsingOnline

Brief title
There is no short title for this study

Condition

- Joint disorders

Synonym
hand osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: EULAR (European League Against Reumatism)

Intervention

Keyword: hand, instruments, osteoarthritis, outcome measures

Outcome measures

Primary outcome

Factors that influence functioning in daily life of patients with HOA from the

perspective of patients.

If the content of these instruments covers the spectrum of concepts important

to patients with HOA.

Secondary outcome

Not applicable

Study description

Background summary

Osteoarthritis is a common joint disorder characterized by progressive loss of articular cartilage and it frequently involves the hand joints. The disease leads to pain in and around the affected joints, swelling, stiffness and loss of function.

In order to evaluate hand osteoarthritis (HOA) various outcome measures and corresponding instruments are available. However, these instruments are developed by professionals without taking patients perceptions on their disease into account. It may be questioned whether the content of these instruments covers the spectrum of concepts important to patients with HOA.
It is important to include the patients perspective because values for outcomes may vary between and among patients and professionals and the effect of treatment needs to be relevant to patients and their quality if life.

Study objective

The aim of this study is to explore the validity of outcome measures and corresponding instruments from the perspective of patients with HOA in order to guide further improvement of existing instruments and development of new instruments.
Outcomes relevant for the functioning of patients with HOA in daily life will be defined. Based on these concepts evaluation of existing instruments will take place and suggestions for improvement of existing instruments and developement of new instruments will be formulated.

Study design

A European multi-centre qualitative focus-group study will be performed. Patients will be invited for an interview in a group with a maximum of seven patients with HOA, a focusgroep. The advantage of a focusgroup is that it allows for interaction and discussion about the aspects important to patients with HOA and the influence of the disease on functioning in daily life. The focusgroup interview will take 1.5 to 2 hours.
The focusgroup interview will de tape recorded and transcribed verbatim. The interview text will be analysed for the influence of HOA on functioning in daily life and possible health related problems due to this disease.

Study burden and risks

There are no risks for patients in this study.
The only burden for patients is the time spend on the focusgroup interview, which is 2 hours.

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

Patients have to meet the ACR (American College of Rheumatology) criteria for hand osteoarthritis. Furthermore, patients are also eligible to participate in this study if they have bony swelling of at least one IP-joint of the second to fifth finger and/or pain or bony swelling of at least one CMC I joint.

Exclusion criteria

For The Netherlands: Inadequate understanding of the Dutch language

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):	01-05-2007
Enrollment:	14
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL17637.058.07