Back complaints in the elderly: clinical course and prognostic factors.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON35201

Source
ToetsingOnline

Brief title
Back complaints in the elderly

Condition

- Musculoskeletal and connective tissue disorders NEC

Synonym
back ache, back pain

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Back pain, elderly, predictive factors, primary care

Outcome measures

Primary outcome

The primary outcome measures are back pain (NRS), disability (Roland Disability Questionnaire RDQ; loss of productivity (PRODISQ)), quality of life (short form 36 (SF-36)) and self-perceived recovery (7-point scale).

Secondary outcome

To identify possible predictive prognostic factors, information will be collected on demographics (age, gender, ethnicity, smoking, alcohol use, education, type of job and marital status), co-morbidity (self-administered comorbidity questionnaire (SCQ) and GP charts), depression (depression scale (CES-D)), kinesiophobia (fear avoidance beliefs questionnaire (FABQ), pain catastrophizing (PCS), back beliefs (back beliefs questionnaire, BBQ), pain response to activities and position (PRAP), widespread pain (ACR-criteria), sleep quality, expectations on recovery (5-point scale), medical consumption, physical activity (IPAQ-short), physical workload (Dutch musculoskeletal questionnaire (DMQ)), and satisfaction with job, with health care and with the patients* current physical condition (5-point scale). During a physical exam, neurological symptoms, muscle strength, spinal deformities, bone mineral density (heel densitometry), infection markers (CRP, c-reactive protein), mobility (timed-up-and-go and 10m walking test), as well as the presence of *red flag* symptoms and the history of back pain will be further assessed. Vertebral degeneration will be quantified based on X-rays. Underlying severe

pathology (malignancy, infection, fracture, severe neurological compromise, inflammatory spondylarthritis) will be registered based on GP charts. In order to be able to perform additional analyses such as genetic polymorphisms in a later phase of the study the remaining blood samples will be kept frozen and stored.

Study description

Background summary

Back pain is the most common musculoskeletal complaint in the elderly and induces profound disability and economical costs. However, the clinical course of back pain in the elderly remains largely unknown. Furthermore, the presence of underlying pathology, and the predictive prognostic factors for developing chronic back pain have received little scientific attention.

Study objective

The objective of the current study is two-fold. First, to identify the duration and severity of back pain in the elderly. Second, to identify possible predictive prognostic factors for developing chronic back pain.

Study design

In a prospective cohort design, 1000 patients will be followed for a period of 1 year. All patients will undergo a standardised physical examination, X-ray investigation, and will fill-out a questionnaire at baseline, based on the MMICS proposal. At 6 weeks and 3, 6, 9, 12, 24, 36, 48 and 60 months after inclusion, patients will fill-out follow-up questionnaires. At 5 years follow-up all patients will undergo a X-ray of their back, similar as the baseline.

Study burden and risks

The risks and burden for the patient are relatively minor. Patients are required to pay a single visit to a research location in their vicinity. Furthermore, they undergo a physical examination, a venapunction, X-ray investigation (at baseline and at 5 years follow-up) and are required to fill out several questionnaires. This will cost the patient a total of 6 hours over the duration of 5 years. The patients will be guided throughout the study and

assistance with filling out the questionnaires can be provided. The information that the study will collect will probably aid in the earlier detection and better treatment of chronic back complaints in the elderly. A complaint which is generally considered to be very disabling.

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, older than 55 years, who visit their GP in the region of Rotterdam with a new episode of back pain (from mid-thoracic downwards). A new episode of back pain is defined as current back pain, preceded by a period of 6 months without consulting the GP for similar complaints.

Exclusion criteria

Patients will be excluded from the study if they do not have enough cognitive capacities to fill out the questionnaires (f.e. due to dementia) or have difficulties speaking and writing the Dutch language. Patients that have severe mobility impairments (f.e. are wheelchair bound) are excluded as well.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-04-2009
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	23-03-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	02-12-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	14-02-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL24829.078.08