Traumatic and non-traumatic knee complaints in general practice: 6-year follow-up of the HONEUR knee cohort

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational invasive

Summary

ID

NL-OMON33951

Source
ToetsingOnline

Brief title
Knee cohort follow-up

Condition

- Tendon, ligament and cartilage disorders

Synonym
knee complaints

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: course, general practice, knee complaints, prognosis

Outcome measures

Primary outcome

The main study parameter is the long-term clinical course in patients who consulted their general practitioner 6 years ago with a new episode of knee complaints. The main endpoint is the amount of patients with persisting or recurrent knee complaints after 6 years of follow-up.

Secondary outcome

Secondary parameters are possible prognostic factors for persisting or recurrent knee complaints after 6 years of follow-up. A secondary endpoint of this study is the amount of patients with osteoarthritis (or degenerative symptoms) of the knee, in patients who had visited the general practitioner 6 years ago with traumatic or non-traumatic (36 year and older at baseline) knee complaints.

Study description

Background summary

A prospective, observational cohort study has started in 2002 on the department of general practice of the Erasmus MC. Participating patients (n=1068) visited their general practitioner (within the academic HONEUR research network) with a new episode of knee complaints and were followed for a period of one year. After one year of follow-up, 50% of the patients with non-traumatic knee complaints and 25% of the patients with traumatic knee complaints had persistent complaints. Because of the high percentages persistent knee complaints after one year of follow-up, the possibility of recurrent knee complaints and to know the long-term outcome of knee complaints, it is important to perform a long-term follow-up (6 years) of the HONEUR knee cohort.

Nowadays a long-term follow-up of patients with knee complaints is lacking entirely.

Study objective

The primary objective of this study is to determine the long-term clinical course in patients who consulted their general practitioner 6 years ago with a new episode of knee complaints. The secondary objectives of this study are to determine prognostic factors for persisting or recurrent knee complaints, the role of the general practitioner in patients with long-term knee complaints, the predictive value of an MRI in patients with traumatic knee complaints and the predictive value for developing degenerative symptoms of the knee.

Study design

The study concerns a long-term follow-up (6 years) of patients within the HONEUR prospective observational cohort study. Data will be collected with a questionnaire, physical examination, X-ray and/or MRI of the knee.

Study burden and risks

The risk to the subject will be minimal, because the research will exist of the usual care, except filling out an questionnaire. Burden for the subject will also be minimal, except X-ray radiation, and will be mainly exist of time for filling out a questionnaire, under wending a physical examination, an X-ray and an MRI (last three only in subgroups). The X-ray radiation will be minimized through taking the X-ray onetime and using the results of an X-ray made in the last year. There will be no direct benefits for the patients in this study.

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

At baseline, patients aged 12 years or above, consulting their general practitioner for a new episode of knee complaints, were invited to participate in the HONEUR study. All patients who had participated at baseline will be included in this 6 year follow-up study. These patients will be 18 years and older at the 6 year follow-up study.

Exclusion criteria

At baseline, patients with knee complaints that required urgent medical attention, patients with malignancies, neurological disorders or systemic musculoskeletal diseases, as well as patients that were incapable of understanding the ramifications of participation, were excluded from participation. Patients who have indicated in the past that they wish not longer to participate in the study will be excluded in this 6 year follow-up study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-03-2009
Enrollment:	748
Type:	Actual

Ethics review

Approved WMO

Date:	16-03-2009
Application type:	First submission
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	NL25024.078.08