Axial Spondyloarthritis in Primary care patients with chronic low back pain; a cross-sectional stratified validation study

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The identification of axial SpA in the primary-care setting and the introduction of questionnaires that could optimize the pattern of referral to secondary care is one of the most important objectives of the CAFASPA-II study.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON35785

Source
ToetsingOnline

Brief title
CAFASPA-II

Condition

- Joint disorders

Synonym
Inflammation of the axial joints, Spondylarthropathy

Research involving
Human

Sponsors and support

Primary sponsor: The Rotterdam Institute of Rheumatology
Source(s) of monetary or material Support: Bedrijf : The Rotterdam Institute of Rheumatology

Intervention

Keyword: Case-finding, General Practice, Spondylarthropathy, Validation study

Outcome measures

Primary outcome

The primary objective of the CAFASPA-II study is three-fold

1.Validate the prevalence of aSpA in young patients with Chronic Low Back Pain (CLBP)

2. To estimate the prevalence's of axial SpA in patients with chronic low back pain in three strata of symptom duration (3 months - 1 year, 1-5 years, > 5 years of having CLBP)

3. To perform external validation on the recently developed referral tool for GP's to identify patients at risk for aSpA.

Secondary outcome

The secondary objectives are :

1. to estimate the additive value of the presence of "Red Flags" in patients with aSpA.

2. to get insight on the specificity (false positive findings) OF MRI OF THE SACROILIAC JOINTS IN PRIMARY CARE.

3. development of questionnaires that differentiate between inflammatory and non-inflammatory back pain in relation to the diagnosis of SpA will be compared

with a view to creating a simple referral model for SpA that can be applied in

the primary-care sector.

Study description

Background summary

*Chronic low back pain:
CAse-Finding Axial SPondyloArthropathy in general practice* (CAFASPA-II)

Recent years have seen a substantial improvement in the prognosis of patients with axial spondyloarthropathy (SpA) due to the advent of new drugs and the intensive use of existing drugs. It is important to ensure that the right medication is instituted early in the disease process. The stumbling block as far as early recognition is concerned is the absence of specific factors on which to base the diagnosis. Furthermore, there is a seven-year delay before abnormalities pathognomonic of sacroiliitis are visible on a conventional x-ray. Predictive models have recently been developed for early recognition of SpA, but these are based on patients who had already been referred to secondary care and closer analysis shows that these patients had also already suffered from inflammatory back pain for 7.7 years. Therefore, future research should focus on early detection of SpA.

Study objective

The identification of axial SpA in the primary-care setting and the introduction of questionnaires that could optimize the pattern of referral to secondary care is one of the most important objectives of the CAFASPA-II study.

Study design

This is a cross-sectional observational validation trial which will be performed in close cooperation with GPs.

Prior to inclusion in the study, potential subjects are screened successively by a GP, research assistant and investigator. Patients who exhibit features of chronic low back pain will be examined for the presence of axial Spa and, if necessary, treated in accordance with the guidelines. For patients with chronic low back pain, in addition to completing questionnaires, the trial consists of blood testing, x-ray examination and magnetic resonance imaging (MRI) of sacroiliac (SI) joints. General practice groups will be invited to take part in the study. It is expected that around 800 patients will be recruited in this period. This number is considered sufficient to answer the questions that the

trial seeks to address.

Study burden and risks

Patients will be fully informed about the aim of the study and also about the circumstances of the individual examination, the amount of time required and the potential risks. The burden for the patient consists of the time spent (questionnaires, physical examination), the provision of 32 ml of blood and the need to undergo an x-ray and MRI of the SI joints.

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-Specific low back pain
Symptom duration more than 12 weeks
Age between 20-45

Exclusion criteria

Impossible to communicate
Low back pain due to trauma
Pregnancy
Metal protheses
Claustrofobia
Unwilling to participate in MRI

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-06-2011
Enrollment:	800
Type:	Actual

Ethics review

Approved WMO

Date:	19-05-2011

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL35718.060.11