The IMPACT of a referral model for axial spondyloarthritis in young patients with chronic low back pain

Published: 17-04-2014
Last updated: 22-04-2024

To evaluate the clinical impact of the CaFaSpA referral rule in young patients presenting at the general practioners with chronic low back pain, who are at risk for axSpA, compared to usual care.

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

Summary

ID

NL-OMON40144

Source
ToetsingOnline

Brief title
IMPACT study

Condition

- Joint disorders

Synonym
Axial spondyloarthritis, reumatic back disorder

Research involving
Human

Sponsors and support

Primary sponsor: Maasstad Ziekenhuis
Source(s) of monetary or material Support: The Dutch Institute of Rheumatology BV

Intervention

Keyword: Axial spondyloarthritis, Impact analysis, Low back pain, Referral rule

Outcome measures

Primary outcome

The primary outcome is a change in the Roland Morris Disability Questionnaire (RMDQ) compared to baseline in the CLBP patients with or without use of the referral model after 4 months.

Secondary outcome

Quality of life measurements (SF-36), cost-effectiveness (EQ-5D, iPCQ, iMCQ), pain and fatigue (VAS), psychosocial tests (Tampa scale for kinesiofobia, Fear avoidance beliefs questionnaire, Hospital Anxiety Depression Scale), referral to rheumatologist and diagnosis of axSpA.

Study description

Background summary

Axial spondyloarthritis (axSpA) is an inflammatory back pain disorder affecting up to 24% of young chronic low back pain (CLBP) patients. For GPs it is difficult to distinguish axSpA patients in the large amount of CLBP patients. In the CaFaSpA 1 and CaFaSpA 2 study a referral rule for axSpA applicable in CLBP patients was developed and validated. The next step is to investigate the impact of the referral rule in daily practice. This impact analysis will test if the referral rule will be beneficial or harmful.

Study objective

To evaluate the clinical impact of the CaFaSpA referral rule in young patients presenting at the general practioners with chronic low back pain, who are at risk for axSpA, compared to usual care.

Study design

A cluster randomized clinical trial.

Intervention

GP are randomized either to use or not to use the CaFaSpA referral model. The CaFaSpA referral models consists out of four variables, a positive ASAS IBP questionnaire, a positive family history for SpA, a good reaction to NSAIDs and back pain duration longer than 5 years. If at least two out of four variables are present a referral to the rheumatologist is advised.

Study burden and risks

The burden and risks associated with participation are minimal. No medical intervention is taken place. If the GP of the patients is randomized to the referral model, the patient is checked for the risk of axial spondyloarthritis, by the non-invasive referral model. If the referral model is positive a referral to the rheumatologist is advised. Is the GP is randomized to the *usual care* there is no difference in the treatment of low back pain than nowadays. A GP is still allowed to treat the CLBP patients optimal and a referral to the rheumatologist is allowed but not actively advised.
All participating CLBP patients are asked to fill several questionnaires at four different time points, at baseline, after 12 months and after 24 months. In total there are 8 questionnaires and four separate questions. The questionnaire are designed to fill out by the patient themselves. The total time to fill in the questionnaire is estimated to be 30 minutes.
The benefits of the study are:
- For the CLBP patients, up to 24% of the back pain complaints are caused by axSpA, but the GPs are not (yet) aware of this disease. When a CLBP patient is participating in this study, the chance of having axSpA as cause for the back pain is investigated. This a benefit for a CLBP patients since there is effective treatment for axSpA.
- For the GP it is very difficult to distinguish an axSpA patients in the large amount of CLBP patients. If it appears that the validated CaFaSpA referral rule has an impact on CLBP and GPs, the next step will be implementation of this referral model in daily practice and it will become a helpful tool for the GP.
- For the society, CLBP is a great socio-economic burden for the society. When one of the causes for CLBP, namely axSpA is diagnosed and treated in an earlier stage this will lead to a decreased sick leave because of back pain and is therefore potentially cost-effective.

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

• Aged 18-45 years
• ICPC L03, non-specific low back pain
• > 12 weeks of low back pain
• Mentally competent
• Understanding of the Dutch language (written)
• Willing to sign informed consent

Exclusion criteria

• A cause for the back pain (like trauma, hernia nuclei pulposi, malignancy, etc)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-07-2014
Enrollment:	4500
Type:	Actual

Ethics review

Approved WMO Date:	17-04-2014
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	07-01-2015
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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
Other	EudraCT number: 2013-003838-32 en NCT nummer: NCT01944163
CCMO	NL45686.101.13

Study results

Date completed:	04-10-2017
Actual enrolment:	679