Implementation of fysical function tests in the usual care of patients with axial spondyloarthritis .

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The objective of this study:The overarching object of this study is to assess if the three tests for physical functioning ('together ASPI measurement') are reliable for patients with (early or suspicion of) axial spondyloarthritis and to...

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

Summary

ID

NL-OMON47505

Source
ToetsingOnline

Brief title
ASPI study

Condition

- Joint disorders

Synonym
M. Bechterew, NR Axial Spa and Axial Spa

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: grant van Pfizer

Intervention

Keyword: Axial spondyloarthritis, function tests

Outcome measures

Primary outcome

Primary outcome measures are:

* Time needed to perform all separate tests in seconds, measured with a stopwatch, by the researcher.

* Time needed to complete the whole test protocol in seconds, measured with a stopwatch by the researcher.

* Pain and effort experienced by the patient during the performance of the tests, questioned with a questionnaire by the researcher

* Verdict of the patient about the test performances, questioned with a questionnaire by the researcher

* The interobserver agreement

* The verdict of the patient about the original and renewed ASPI instructions

Secondary outcome

Does not apply

Study description

Background summary

Axial spondyloarthritis (axSpA) manifests itself between the 20th and 40th year of life and is part of a rheumatic inflammation that causes pain, stiffness, structural and functional impairments of the spine, pelvis and joints. Ax-SpA includes ankylosing spondylitis (AS) and non-radiographic axial

spondyloarthritis (nr-axSpA) where no visible radiographic sacrolitis and ossification is.
Consequently of the disease, physical activities like picking something of the ground and putting on socks become harder to accomplish. The most important objectives of treatment are to keep or improve the physical function in patients. For this reason physical function is an important outcome measurement to assess disease progression and treatment effects.
It is difficult to assess disease progression and treatment effects objectively. The most important outcome measurements are based on questionnaires, since (i) blood measurements/ acute phase responses like BSE and CRP were not increased/specific for SpA despite many complaints and (ii) the progression of structural damage on radiological images are a slow process and therefore not very sensitive for changes on short follow up. The minimal follow up time to estimate the radiological damage is two year.
Both in research as in daily clinical practice, physical function is measured with the BASFI questionnaire (Bath AS Functional Index). This questionnaire measures the patients* perception of their ability of physical functioning, which can lead to an over- or under estimation of the real physical function ability. The discrepancy between the patients* perception and the real ability of physical function can be influenced by needs, priorities, cognitive functioning, culture, language, education, character, depression and pain. In patients with axSpA a strong relation was found between psychological variables (helplessness, depression and passive coping style) and the BASFI questionnaire score. Thereby, both the BASFI and BASDAI scores (self-reported measurement for disease activity) often show large and quick variations over time.
Therefore, an objective measurement is needed to assess the physical function with no or less influence of the patients* experience.
Despite there are good treatment strategies (biologicals), no objective outcome measurements are available to measure the improvement in physical function. Physical tests (performance-based tests) where the patient must perform the activity instead of filling in a questionnaire of the patients* perception if they can perform the activity fulfills this need.
Recently, 8 performance based test were developed for ax-SpA, based on activities described in the BASFI questionnaire. In these tests the time of complete an activity and level of effort a patient experienced were measured. It seems that the tests were reliable and result in other information than the BASFI questionnaire. After a three month intervention with biologicals, the tests show a significant improvement in the physical functioning, even in patients who did not response according to the response criteria (ASAS20%). These results show that self-reported questionnaires and performance-based tests measured different aspects of physical function. The tests gave a valuable information in addition on the usually BASFI questionnaire and add something to the term physical function in axSpA.
Because it is expensive, a lot of effort and time consuming to do all the 8 performance-based test a selection of the tests were made. There were 3 tests selected that seems to be the most sensitive for changes and were the most user friendly for clinical practice. The tests include 1) picking up pencils,

2) putting on socks, 3) stand up from the ground. The combination of these tests termed axial spondylarthritis performance-based improvement index (ASPI). However, the usability and applicability of the test selection must be confirmed in daily practice and in a brother spectrum of SpA patients. The physical function tests were developed en tested in AS patients and it lacks information about the use of these tests in nr-axSpA patients. In nr-axSpA patients it is even harder to find disabilities in physical functioning, because beside the many complaints, clinical observational features like inflammations in blood, MRI and imagines are mostly absent. The use of ASPI could be the first step to assess also in nr-axSpA the level of change in physical functioning and can be therefore a valuable addition on the existing outcome measures.

Study objective

The objective of this study:

The overarching object of this study is to assess if the three tests for physical functioning ('together ASPI measurement') are reliable for patients with (early or suspicion of) axial spondyloarthritis and to assess the feasibility in daily clinical practice in addition to the BASFI questionnaire.

The aforementioned overarching objective will be assessed through the following sub objectives:

1. The reliability and measurement error of the ASPI in nr-axSpA patients that start with a biological.
2. The responsiveness of the ASPI in nr-axSpA patients that start with a biological.
3. Natural variance of the ASPI in nr-axSpA patients that are stable on medication (> 6 weeks NSAID of 3 months biologicial).
4. Natural variance of the ASPI in AS patients stable on medication (> 6 weeks NSAID of > 3 months biological).
5. The usability and applicability (terms of time and satisfaction) of the ASPI in AS and nr-axSpA patients.
6. The inter-observer reliability of the ASPI.
7. The evaluation of the applicability of the ASPI in daily clinical practice (by patient and researcher).
8. Evaluation of the understandability of the original ASPI patient instructions and the more extensive (new) ASPI patient instructions improve the understandability.
9. ASPI sensitivity to detect changes in fysical function in "early" axSpA patients.

Study design

An observational study will be performed where subjects were measured during their regular visits in the VUmc at the rheumatology department. The following design will be used:
Objective 1: Test-retest on time measurements t=0 and t=1 week
Objective 2: Test-retest on t=0 and t=3 months
Objective 3: Test- retest t=0 and t=3 months
Objective 4: Test- restest t=0 and t=3 months
Objective 5: All measurements for the purpose of objectives 1-4, will be beside the time per separate measurement, in addition the time measuerd that is needed to complete the set of three tests.
Objective 6: Inter-observer reliability on t=0 and t=3 months. The ASPI will be performed by both observers with at least ten minutes between the two performances. The sequence of the observers that perform the ASPI is alternated (once observer 1 as first and second time observer 2 as first)
Objective 7: Evaluation of the ASPI in daily clinical practice, by the patient and the ASPI researcher. For this the patient will be asked to fill in a questionnaire about several aspects of the test performance and take the tests.
Objective 8: The understandability of the original ASPI patient instructions will be evaluated and assessed if the more extent version of the (new) ASPI instructions improve the understandability. This will be assessed when the patient performs the ASPI test for the first time. First the original instructions will be read aloud and subsequently asked to the patient (yes/no): *Is it clear what you need to do?* and, if the answer is *no*: *Which information did you miss?*. Subsequently, the more extent version will be read aloud and the same questions will be asked to the patient: *Is it clear what you need to do?*, (if the answer is no): *Which information did you miss?* and *Do you think these new instructions are better compared to the old ones?*.

Objective 9: patients perform every 6 months the ASPI during their visit to the poli clinic. For this objective sutdy patients will be included that are approached for the sp-EYE study. The Sp-EYE study is a non-WMO complicity prospective observational cohort study (non-WMO number:2017.037). For this patient- and disease data will be prospectively obtained and the patient will complete questionnaires every six months. It concerns patients who were referred by the eye physician between march 2017 and march 2018, because of suspicion of axial SpA, based on uveitis anterior and chronical back pain. The expectation is that approximately 170 patients will be included. These patients will be approached by their physicianafter there first presentation on the rheumatology policlinic for participation in the Sp-EYE study (informed consent procedure). At the same time patients will also be informed about the ASPI study (part B).

The ASPI will be performed after the regular visits to the VU medical center. From time point 0 (t=0), about every 6 months till latest t=24 months. Because the Sp-EYE study has a observational design (where the clinic is leading for the frequency of policlinical visits and follow-up) not every patient included in the ASPI study will have a follow-up of 24 months.

The study protocol of the Sp-EYE study is add as appendix with submission (appendix A). This appendix contains all the details considering the study background, objectives, population, recruitment method and study parameters. If teh patient consents with participation in the Sp-EYE study, the patient is eligible for participation in the ASPI study (part B). For this participation, separate permission will be asked (separate patient information and separate informed consent). This will only be the case if the ASPI is approved (current protocol), before this only the Sp-EYE study will be discussed.
The ASPI will taken place during the regular policlinical visits (every 6 months), at the same time the study activities for the Sp-EYE are performed. To minimize the study load for the patient, no extra policlinical visits were scheduled for the ASPI. The impost of participation of the ASPI study objective 9, will exist of an extension of the regular visit for the Sp-EYE study of 10 minutes (beside the extenstion of 10-15 minutes for the Sp-EYE study). The current protocol focus will only be on the study design of part A. All other relevant information concerning part B can be found in the study protocol of the Sp-EYE study, non-WMO number 2017.037, appendix A. The ASPI study will not be discussed in the Sp-EYE protocol, since the ASPI is part of a WMO protocol.
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Study burden and risks

Subjects must in addition to the regular visits perform, twice, three performance-based tests including 1.) picking up six pencils, 2.) putting on socks (3x), 3.) stand up from the ground (mat) (3x). Thereby, patients explained with each test how much pain and exhaustion they experienced. At the end, patients were ask to fill in a questionnaire where is asked to their opinion of the performance of the tests (change, satisfaction and effort).

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 18 - 70 years
Diagnosed with NR-axSpa or Spa

Exclusion criteria

When informed consent is not given

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-12-2017
Enrollment:	51

Type:	Actual

Ethics review

Approved WMO Date:	23-06-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL58524.029.16