Sensitive Imaging in Ankylosing Spondylitis

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* To study the relationship between inflammation on MRI and syndesmophyte formation with very detailedimaging methods: radiography, computed tomography (CT), 3 and 7 Tesla MRI. * To examine the time order of pathologic changes like inflammation,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON39151

Source
ToetsingOnline

Brief title
SIAS

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Autoimmune disorders
- Tendon, ligament and cartilage disorders

Synonym
Ankylosing Spondylitis, Bechterew disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: Ankylosing Spondylitis, Computed Tomography, Magnetic Resonance Imaging, Radiography

Outcome measures

Primary outcome

To study whether there is a relationship between local inflammation and the development of new syndesmophytes at the same site in a vertebral unit in patients with ankylosing spondylitis:

• Direct causal relationship: local inflammation * syndesmophyte formation

• Indirect causal relationship: inflammation * local changes * resolved inflammation * syndesmophyte formation

Secondary outcome

• To examine the time order of pathologic changes (e.g. inflammation, fatty degeneration, erosion, syndesmophyte formation).

• To examine the exact location of inflammation in a vertebral unit.

• To test the hypothesis that syndesmophyte formation occurs at sites with complete normal anatomy without inflammation.

• To assess the agreement between 3 and 7 Tesla MRI in detecting sites of inflammation

• To assess the agreement between CT and conventional radiography of the cervical and lumbar spine in detecting structural changes.

• To examine if the thoracic spine provides different information compared to the cervical and lumbar spine.

Study description

Background summary

Ankylosing spondylitis (AS) is an inflammatory disease characterized by chronic inflammation in the spine. Ultimately, patients develop syndesmophytes, bony spikes at corners of vertebrae resulting in bony bridges. Conventional radiography is able to visualize syndesmophyte formation, which can already be detected after a one year interval. However, two years are advised to see sufficient changes in many patients. Inflammatory changes can already be detected using magnetic resonance imaging (MRI) in an earlier disease stage. The general hypothesis is that inflammation precedes bone formation; however, currently available data do not support this hypothesis. There is no relationship between the overall level of inflammation in the spine and the number of new syndesmophytes. Detailed analyses of vertebral inflammation and syndesmophyte formation in the same unit show that it is slightly more likely that syndesmophytes are formed in vertebrae with inflammation compared to those without inflammation. However, the majority of syndesmophytes are formed in vertebrae in which no inflammation was present over a two year period. Anti-TNF agents are very effective in suppressing MRI inflammation, but are unable to inhibit syndesmophyte formation.

Study objective

* To study the relationship between inflammation on MRI and syndesmophyte formation with very detailed
imaging methods: radiography, computed tomography (CT), 3 and 7 Tesla MRI.
* To examine the time order of pathologic changes like inflammation, fatty degeneration, erosion and syndesmophyte
formation.
* To assess agreement between 3 and 7 Tesla MRI in detecting inflammation.
* To assess agreement between CT and conventional radiography of the cervical and lumbar spine in detecting
structural changes.
* To examine if the thoracic spine provides different information compared to the cervical and lumbar spine.

Study design

This is a prospective follow-up study using a cohort of patients with ankylosing spondylitis. Consenting patients will have both clinical and radiological assessments. Patients will be studied over a two year period with annual (MRI) and biennial (radiography, CT) imaging of the spine.

Study burden and risks

Thirty patients with Ankylosing Spondylitis will be studied for a period of 2 years. Each visit (to a total of 3) will take about 4 hours.

Visit 1 (t=0)
* department of rheumatology: interview, physical examination, questionnaires, venous punction
* department of radiology: X-CWK / X-LWK / CT-scan / 3 Tesla MRI -scan/ 7 Tesla MRI-scan

Visit 2 (t=12 months)
* department of rheumatology: interview, physical examination, questionnaires, venous punction
* department of radiology: 3 Tesla MRI -scan / 7 Tesla MRI-scan

Visit 3 (t=24 maanden)
* department of rheumatology: interview, physical examination, questionnaires, venous punction
* department of radiology: X-CWK / X-LWK / CT-scan / 3 Tesla MRI -scan/ 7 Tesla MRI-scan

Burden / risks for the patient:
* Three venous punctions which may be perceived as painful.

* X-rays and CT-scans use radiation. Exposure to radiation is a risk for developing cancer. However, the risk on developing cancer due to X-rays is very small. Concerning the CT-scans: the total radiation dose is estimated to be 2 x 4 msV = 8 msV effective dose. This effective dose is judged as 'high' and places this research in category IIb according to European guidelines. Category IIb states that 'the proposed research has to be judged on the criterion: research of social relevance, meant for diagnosis, treatment of prevention', which is the case in our 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

a) Male and female patients of at least 18 years having Ankylosing Spondylitis (AS) fulfilling the Modified New York criteria, in which a patient has *definite* AS if the radiological criterion is associated with at least one clinical criterion: ;Clinical criterions:
* low back pain and stiffness for more than 3 months that improves with exercise, but is not relieved by rest.
* limitation of motion of the lumbar spine in the sagittal and frontal planes.
* limitation of chest expansion relative to normal values correlated for age and sex.;Radiological criterion (sacroiliitis grade >= 2 bilaterally or grade 3-4 unilaterally)
* grade 0 = no sacroiliitis
* grade 1 = blurring of the joint margins (*suspicious*)
* grade 2 = sclerosis, erosions, no changes in joint space
* grade 3 = erosions, changes in joint space, partial ankylosis
* grade 4 = complete ankylosis;b) Patients should have at least one syndesmophyte in either the cervical or lumbar spine radiograph at baseline conventional radiography. The maximum number of VUs is 9 (out of 12). ;c) The patient should have given written informed consent.

Exclusion criteria

* > 9 by syndesmophytes affected vertebral units.;* A history of alcoholism, drug abuse, psychological or other emotional problems, severe comorbidity likely to invalidate informed consent or limit the ability of the subject to comply with the protocol requirements.;* Routine MRI-contraindications (e.g. instable metal implants, pacemaker/ICD, vascular clips, hearing aids and claustrophobia).;* Pregnancy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	64-section CT scanner
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-06-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	01-05-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL30927.058.09