Impact of ankylosing spondylitis (AS) on social participation and reversibility by anti-TNF-α (adalimumab) therapy

Published: 14-09-2011
Last updated: 27-04-2024

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

Summary

ID

NL-OMON38200

Source
ToetsingOnline

Brief title
AS participation study

Condition

- Joint disorders
- Lifestyle issues

Synonym
Ankylosing Spondylitis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Abbott inc

Intervention

Keyword: Ankylosing Spondylitis, Anti-TNF-&alfa, Participation, Physical activity

Outcome measures

Primary outcome

A decrease in importance satisfaction gap of social participation areas over time in AS patients, due to a decrease of the disease burden, caused by treatment with anti-TNF-α (adalimumab)

Secondary outcome

(2) Understand which disease related and which contextual factors contribute to the change in restrictions of participation and in the gap between importance and satisfaction in participation areas. Several new variables will be assessed, such as: objectively assessed physical activity, body composition, beliefs/attitude regarding physical activity. (3) Changes in physical activity and body composition. Furthermore (4), the relation of participation and satisfaction with life is an important secondary parameter.

Study description

Background summary

Participation is a relevant outcome when exploring the impact of chronic diseases on persons, since it contributes to the individual's autonomy in society and satisfaction with life. In ankylosing spondylitis (AS) research concentrated on participation in paid work, but ignored other important areas of participation such as engagement in physical leisure activities, attending at social events and maintaining relationships with children, grandchildren and other family. Moreover, variables contributing to participation and its relation to satisfaction with life are poorly understood. Among others, physical activity and body composition (related to disease and physical activity) have been raised as underestimated factors. Finally, it is not known

to what extent treatment with anti-TNF- α can improve participation and overall life satisfaction. Insights into these issues will help to improve holistic management of patients with AS, when, aiming to help them continuing an autonomous and satisfied life.

Study objective

Main objectives are first; to explore the reversibility of restrictions and the importance-participation gaps when AS patients with a high disease activity are treated with anti-TNF-α (adalimumab). Second, to explore the effect of anti-TNF-α (adalimumab) on physical activity and body composition in AS and third; examine if they are related to participation.

Study design

9 month prospective cohort (longitudinal) study.

Study burden and risks

Baseline measurements will be compared with outcomes after 12, 24 and 36 weeks. Online questionnaire will assess all the mentioned outcomes at every point in the study. Additionally, physical activity (accelerometers) and body composition (deuterium dilution) will be assessed at baseline and after 36 weeks. All the measurements can be carried out at home or other place of will. No potential risks are expected.

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

- Have AS according to the New York criteria
- Be under the care of a rheumatologist
- Start TNF inhibitors (adalimumab) as being part of current practice
- BASDAI score of 4 or higher.
- All subjects must be recruited within a period of 1 (one) year from the start of the longitudinal study.

Exclusion criteria

- Have severe non-AS related co morbidity according to the diagnose treatment combination (DBC). Please note that this only applies for patients with a co-morbidity, by whom the treating doctor/rheumatologist decides they should not be included in the study because of health reasons. Patients who suffer from a co-morbidity without a non-immediate health risk will be included. Their situation will be assesses with the SQC questionnaire in order to correct for a confounding effect.
- Have contra-indications (diagnosed by treating rheumatologist/specialist) for TNF inhibition
- Do not understand the Dutch language
- Do not have access to a computer with internet

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-03-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	14-09-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-12-2011
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	20-01-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	12-03-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	15-03-2012
Application type:	Amendment

Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	19-03-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	05-04-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	13-06-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	15-08-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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	NL35390.068.11