De relatie tussen geslacht, lichaamssamenstelling en het succesvol kunnen verminderen van medicijnen (TNF blokkers) bij patiënten met de ziekte van Bechterew.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21138

Source
Nationaal Trial Register

Brief title
Tap-AS

Health condition

ankylosing spondylitis, Bechterew, TNF blocker, spondylitis ankylopoetica, spondyloarthritis, TNF blokker

Sponsors and support

Primary sponsor: VU university medical center
Source(s) of monetary or material Support: Reumafonds

Intervention

Outcome measures

Primary outcome

the presence of an AS disease flare (ASDAS of 2.1 or higher during at least 2 weeks).

Secondary outcome

- parameters of body composition:
anthropometrical measurements and DEXA parameters (e.g. body fatt, lean mass)

- other parameters of AS disease activity (BASDAI, VAS, BASFI, BASMI, 44 joint count, quality of life)

- the presence of extra articular manifestations

- cardiovascular risk factors

- through levels of TNF inhibitor

Study description

Background summary

Women have been fairly underrepresented in studies of ankylosing spondylitis (AS). This is unfortunate since there are important gender differences in AS and women appear to respond less well to treatment with TNF-alpha inhibitors (TNFi). So far it is unknown whether there are also gender differences in the reaction to tapering of TNFi, while tapering currently becomes more and more standard practise in patients with sustained disease activity. Differences in the response to TNFi (treatment and tapering) could possibly be due to gender differences in body composition.

The current study includes AS patients who start to taper their TNF blocker. Primarily the gender difference in the risk of an AS disease flare will be studied, and the association with baseline body composition. The follow up is 1 year.

Study objective

Men and women do not have the same risk of an ankylosing spondylitis (AS) disease flare during tapering of their TNF blockers. If so, this could probably be associated with differences in body composition.

Study design

Baseline - 3 months - 6 months - 9 months - 12 months (end of study)

Intervention

TNF blockers will be tapered by using a predefined schedule of prolongation (doubling) of the dosinginterval.

Also: a whole body DEXA scan will be performed (2x) and blood samples will be collected

Contacts

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Eligibility criteria

Inclusion criteria

• 18 years or older

• AS (radiographic axial spondyloarthritis) according to the 1984 modified New York Criteria

• Use of a TNF-alpha blocker, stable dose during the last 6 months

• ≥6 months: Low (inactive or moderate) disease activity based on the ASDAS-CRP (<2.1) or, if unavailable, according to the clinical evaluation of the treating physician.

• At study entrance: ASDAS <2.1.

Exclusion criteria

• Planned reasons for treatment discontinuation (e.g. pregnancy)

• Unable to understand the study aims and methods

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-12-2017
Enrollment:	190
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-12-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46502
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6674
NTR-old	NTR6844
CCMO	NL62504.029.17
OMON	NL-OMON46502

Study results