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

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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.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON21138

**Bron**
Nationaal Trial Register

**Verkorte titel**
Tap-AS

**Aandoening**

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

### Ondersteuning

**Primaire sponsor:** VU university medical center
**Overige ondersteuning:** Reumafonds

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

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

# Contactpersonen

## Publiek

Postbus 7057, 1007 MB Amsterdam

I.E. van der Horst-Bruinsma
De Boelelaan 1117, 1081 HV Amsterdam
Amsterdam 1081 HV
The Netherlands
0031 (0)20 4445085

## Wetenschappelijk

Postbus 7057, 1007 MB Amsterdam

I.E. van der Horst-Bruinsma
De Boelelaan 1117, 1081 HV Amsterdam
Amsterdam 1081 HV
The Netherlands
0031 (0)20 4445085

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

## Belangrijkste redenen om niet deel te kunnen nemen

### (Exclusiecriteria)

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

• Unable to understand the study aims and methods

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 06-12-2017 |
| Aantal proefpersonen: | 190 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 05-12-2017 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46502

Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

# Resultaten