Afbouw strategieën bij door anti-TNF&MTX geïnduceerde remissie bij Reumatoïde Arthritis. Moeten we MTX of anti-TNF als eerste afbouwen?

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In RA patients that achieved disease remission by treatment with the combination of a csDMARD and anti-TNF, there is a difference in (cost-)effectiveness when medication is tapered according to strategy A (csDMARD first) compared to strategy B (anti...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21808

Bron
NTR

Verkorte titel
TARA

Aandoening

Rheumatoid Arthritis

Ondersteuning

Primaire sponsor: Erasmus MC, Rotterdam
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Number of flares in each arm;
2. Incremental Cost Effectiveness Ratio (ICER) of one strategy over the other.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Economic evaluation of tapering medication in Rheumatoid Arthritis (RA) is important because of the increasing use of expensive biologicals in the treatment of RA. Previous uncontrolled cohort studies showed that it is possible to taper the anti-TNF or the csDMARD while maintaining remission of disease in approximately 40% of the rheumatoid arthritis (RA) patients that use the combination of csDMARD&anti-TNF. This is not yet common practice which may relate to the fact that it is unclear which step down (tapering) regime would be optimal. There are no head-to-head studies available comparing the tapering of the csDMARD with tapering of anti-TNF in csDMARD&anti-TNF using patients in clinical remission.

Objectives:

Our main aim is to evaluate the effectiveness and cost-effectiveness of two tapering strategies:(i)csDMARD tapering and (ii)anti-TNF tapering in RA patients with csDMARD&anti-TNF induced remission.

Study design:

A multicenter randomised single-blind controlled trial with a parallel cost-effectiveness study will be set up to compare the outcomes of the 2 tapering strategies over a 2-yr period.

Study population:

RA patients, aged>17 years, treated with a csDMARD & TNF-inhibitor, DAS<=2.4&SJC<=1 for two consecutive time points (3 months), being able to understand, speak and write in Dutch and having no psychiatric or personality disorders. Patients will be excluded if they need to

taper or stop their medication due to other reasons such as the wish to get pregnant or a scheduled surgery.

Intervention:

Two tapering strategies will be evaluated.

Tapering csDMARD first: The baseline dosage of the csDMARD will be tapered in two steps over 12 months. In the first 3 months the dosage of the csDMARD will be reduced to half the baseline dosage, after 3 months the dose is tapered to a quarter of the baseline dosage. Thereafter the csDMARD will be stopped. Anti-TNF will be continued throughout the first year. In the second year the baseline dosage of anti-TNF will be tapered in two steps over 6 months. In the first step the dosage will be halved by doubling the interval between gifts. In the second step (after 3 months) the baseline dose will be reduced to a quarter of the baseline dose by cutting the dose into half. Thereafter the anti-TNF treatment is stopped.

Tapering anti-TNF first: The baseline dosage of anti-TNF will be tapered in two steps over 6 months. In the first step the dosage will be halved by doubling the interval between gifts. In the second step (after 3 months) the baseline dose will be reduced to a quarter of the baseline dose by cutting the dose into half. Thereafter the anti-TNF treatment is stopped. Baseline csDMARD dosage will be continued throughout the first year. In the second year, the baseline dosage of the csDMARD will be tapered in two steps over 12 months. In the first 3 months the dosage of the csDMARD will be reduced to half the baseline dosage, after 3 months the dose is tapered to a quarter of the baseline dosage. Thereafter the csDMARD will be stopped.

Tapering will be terminated if the DAS >2.4 and/or SJC>1 at one of the 3-month follow-ups. In case of a flare, patients will be put back to the last effective dosage. No further attempts will be taken to taper medication throughout the study. 1 intra-muscular injection with glucocorticosteroids will be allowed each 3-month period.

Primary outcomes of the study:

Primary outcome clinical effectiveness: Disease flare defined as DAS44>2.4 in the first 12 months.

Primary outcome cost-effectiveness: Incremental Cost Effectiveness Ratio (ICER) of tapering csDMARD versus tapering anti-TNF in terms of cost per QALY gained and in terms of cost per tapered patient.

Secondary outcome of the study:

Secondary outcomes will include radiographic progression at 1 and 2 years, the HAQ, the SF36, sick leave, productivity loss at work and cost-effectiveness modeled over the long term.

Doel van het onderzoek

In RA patients that achieved disease remission by treatment with the combination of a csDMARD and anti-TNF, there is a difference in (cost-)effectiveness when medication is tapered according to strategy A (csDMARD first) compared to strategy B (anti-TNF first).

Onderzoeksopzet

1. 3-monthly evaluation of disease activity and collection of questionnaires;

2. 2 years of follow-up.

Onderzoeksproduct en/of interventie

Randomization into two arms:

1. Tapering the csDMARD first, then the TNF-inhibitor;

2. Tapering the TNF-inhibitor first, then the csDMARD.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. RA patients;

2. Aged >17 years;

3. Treated with a csDMARD & TNF-inhibitor;

4. DAS44 <= 2.4 & SJC<=1 for two consecutive time points (3 months).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Not being able to understand, speak and write in Dutch;

2. Being diagnosed with a psychiatric or personality disorder.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2011
Aantal proefpersonen:	355
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-02-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2625
NTR-old	NTR2754
Ander register	ZonMw : 171102014
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
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