Prevention of MTX induced psychological intolerance in children with Juvenile Idiopathic arthritis.

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25952

Bron
NTR

Verkorte titel
Gastrointestinal side effects of MTX in patients with JIA

Aandoening

Patients with JIA (all subtypes) aging 4 to 17 years

Ondersteuning

Primaire sponsor: none (investigator driven)
Overige ondersteuning: unrestricted grant to NM Wulffraat from Medac and Pharmachmie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The number of patients continuing MTX;
2. Number of patients reporting gastrointestinal side effects;
3. JIA disease activity parameters.
Measured: 0, 3, 6 and 12 months.

Toelichting onderzoek

Achtergrond van het onderzoek

MTX is currently the most widely used, effective, safe and cheapest second line anti-rheumatic drug for the treatment of Juvenile Idiopathic Arthritis (JIA) and Rheumatoid Arthritis (RA). These advantages have made MTX very successful with regard to efficacy and safety for the individual patient as well as for the health care budget.
The downside of MTX is that especially after prolonged use, quite a number of JIA patients turn intolerant for the drug. This intolerance is characterized by severe gastrointestinal complaints that sometimes occur even before taking the drug.
The aim of this study is to explore the incidence of MTX related gastro-intestinal in a large cohort of JIA patients. Secondly, we want to investigate the effect of psychological behavioural therapy or switch to parenteral MTX dosing to ameliorate these side effects. In a pilot study such a behavioural therapy was successful in 11 of 20 JIA patients. These patients could therefore continue the MTX, and did not need to switch to alternative medication (often more immunosuppressive, toxic and very expensive).
Behavioural therapy is easy to apply and safe. In the first month it is time consuming. There are no risks for applying this in children.
The benefit is that we expect that behavioural therapy will ameliorate the intolerance and prevent switch to parenteral MTX (painfull injections) or alternative (more immunosuppressive and more expensive) medication.

Doel van het onderzoek

The aim of this study is to explore the incidence of MTX related gastro-intestinal in a large cohort of JIA patients. Secondly, we want to investigate the effect of psychological behavioural therapy or switch to parenteral MTX dosing to ameliorate these side effects. In a pilot study such a behavioural therapy was successful in 11 of 20 JIA patients. These patients could therefore continue the MTX, and did not need to switch to alternative medication (often more immunosuppressive, toxic and very expensive).

Onderzoeksproduct en/of interventie

Patients will be randomised for
1. Behavioral therapy plus continuation of oral MTX (intervention);
2. Switch to parenteral MTX (control)
3. Continuation of standard of care plus anti-emetic drugs (control).

Contactpersonen

Publiek

University Medical Center Utrecht (UMCU),
Department of Pediatric immunology and rheumatology,
KC 03.063
P.O. Box 85090

N. Wulffraat
Utrecht 3508 AB
The Netherlands
+31 (0)30 2504003

Wetenschappelijk

University Medical Center Utrecht (UMCU),
Department of Pediatric immunology and rheumatology,
KC 03.063
P.O. Box 85090

N. Wulffraat
Utrecht 3508 AB
The Netherlands
+31 (0)30 2504003

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosis: all subtypes JIA according to ILAR classification;
2. Ages 4 to 17 years;
3. MTX oral (dosing 10-20mg/m2/week);
4. Other medication: NSAID, biologicals (etanercept, infliximab, anakinra) allowed.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. MTX parenteral;

2. Other diagnosis;
3. Steroid usage (more than 0.2mg/kg/day);
4. Other MTX related side effects.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2007
Aantal proefpersonen:	130
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL831
NTR-old	NTR844
Ander register	: N/A
ISRCTN	ISRCTN13524271

Resultaten

Samenvatting resultaten
pilot study submitted to Clin Exp Rheumatology