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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25952

Source
NTR

Brief title
Gastrointestinal side effects of MTX in patients with JIA

Health condition

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

Sponsors and support

Primary sponsor: none (investigator driven)
Source(s) of monetary or material Support: unrestricted grant to NM Wulffraat from Medac and Pharmachmie

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. JIA disease activity parameters (PRINTO core set criteria);.
2. Metabolomics and folate/homocysteine/adenosine metabolites;
3. Inflammation parameters (ESR, CRP, cytokine profiles, Tregs, MMR antibodies);
4. MTX related cytopenias.
Measured: 0, 3, 6 and 12 months.

Study description

Background summary

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.

Study objective

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).

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	130
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL831
NTR-old	NTR844
Other	: N/A
ISRCTN	ISRCTN13524271

Study results

Summary results
pilot study submitted to Clin Exp Rheumatology