

# Prevention of methotrexate-induced psychological intolerance in children with juvenile idiopathic arthritis

<b>Submission date</b> 22/01/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/03/2015	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

Prevention of methotrexate-induced psychological intolerance in children with juvenile idiopathic arthritis

## Study objectives

The aims of this study are:

1. To explore the incidence of Methotrexate (MTX) related gastro-intestinal in a large cohort of Juvenile Idiopathic Arthritis (JIA) patients
2. 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).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Medical Ethics Committee of the University Medical Center Utrecht and other participating centers for local feasibility, 21/06/2007, ref: 07/053

## Study design

Randomised parallel-group multicentre trial

## Primary study design

Interventional

## Secondary study design

Randomised parallel trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Juvenile Idiopathic arthritis (JIA)

## Interventions

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)

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Methotrexate

**Primary outcome measure**

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 measures**

1. JIA disease activity parameters (Pediatric Rheumatology InterNational Trials Organisation [PRINTO] core set criteria)
2. Metabolomics and folate/homocysteine/adenosine metabolites
3. Inflammation parameters (Erythrocyte Sedimentation Rate [ESR], C-Reactive Protein [CRP], cytokine profiles, T regulatory [T-regs] cells, Measles, Mumps, Rubella [MMR] antibodies)
4. MTX related cytopenias

Measured: 0, 3, 6 and 12 months.

**Overall study start date**

01/03/2007

**Completion date**

01/03/2010

**Eligibility****Key inclusion criteria**

1. Diagnosis: all subtypes JIA according to International League of Associations for Rheumatology (ILAR) classification
2. Ages 4 to 17 years
3. MTX oral (dosing 10 to 20 mg/m<sup>2</sup>/week)
4. Other medication: Non-Steroidal Anti-Inflammatory Drug (NSAID), biologicals (etanercept, infliximab, anakinra) allowed

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

4 Years

**Upper age limit**

17 Years

**Sex**

Both

**Target number of participants**

130

**Key exclusion criteria**

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

**Date of first enrolment**

01/03/2007

**Date of final enrolment**

01/03/2010

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

University Medical Center Utrecht (UMCU)

Utrecht

Netherlands

3508 AB

**Sponsor information****Organisation**

University Medical Center Utrecht (UMCU) (The Netherlands)

**Sponsor details**

Department of Pediatrics

P.O. Box 85090

Utrecht  
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3508 AB

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.umcutrecht.nl/zorg/>

**ROR**

<https://ror.org/0575yy874>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Pharmachemie (The Netherlands)

**Funder Name**

Medac (The Netherlands)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	18/02/2015		Yes	No