

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

Submission date 22/01/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 22/01/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/03/2015	Condition category Musculoskeletal Diseases	☐ 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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/m²/week)
4. Other medication: Non-Steroidal Anti-Inflammatory Drug (NSAID), biologicals (etanercept, infliximab, anakinra) allowed

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 years

Upper age limit

17 years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Pharmachemie (The Netherlands)

Funder Name

Medac (The Netherlands)

Results and Publications

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?
Results article	results	18/02/2015		Yes	No