ISRCTN13524271 https://doi.org/10.1186/ISRCTN13524271

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

Submission date	Recruitment status	[X] Prospectively registered
22/01/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/03/2015	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr N Wulffraat

Contact details
University Medical Center Utrecht (UMCU)
Department of Pediatric Immunology and Rheumatology
KC 03.063
P.O. Box 85090
Utrecht
Netherlands
3508 AB
+31 (0)88 75 5 4003
N.Wulffraat@umcutrecht.nl

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^2/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
Netherlands
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?
Results article	results	18/02/2015		Yes	No