

Multicentre randomised actively controlled trial of parenteral methotrexate in medium versus low doses in Juvenile Idiopathic Arthritis (JIA)

Submission date 06/01/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 06/01/2003	Overall study status Completed	☐ Protocol
Last Edited 03/11/2011	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof P Woo

Contact details
Department of Molecular Pathology
Centre for Paediatric and Adolescent Rheumatology
Windeyer Institute
UCLMS
46 Cleveland Street
London
United Kingdom
W1T 4JF
+44 (0)20 7436 0783
patricia.woo@ucl.ac.uk

Additional identifiers

Protocol serial number
W0580

Study information

Scientific Title**Acronym**

PRINTO

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Juvenile Idiopathic Arthritis (JIA)

Interventions

All patients started on standard methotrexate therapy, after six months non-responding patients randomised to medium (max 20 mg/week) or high dose methotrexate (max 40 mg /week)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Methotrexate

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2007

Eligibility

Key inclusion criteria

1. Screening phase (pre-randomisation):
 - a. Definite diagnosis of JIA with onset before the 16th birthday (Cimaz & Fink 1996 - http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?holding=f1000&cmd=Retrieve&db=PubMed&list_uids=8882046)
 - b. Patients starting methotrexate for the first time (oral, subcutaneous [SC] or intramuscular [IM] 8-12.5 mg/m² once a week)
 - c. At least two other abnormal variables of any of the six core set parameters. The physician and the parents' ratings must both be at least one on a 10 cm Visual Analogue Scale (VAS), and the Childhood Health Assessment Questionnaire (CHAQ) score greater than zero
2. Trial phase (post-randomisation):
 - a. Only patients who fail to respond to at least four but no more than six months of treatment with a standard dose of methotrexate (oral, SC or IM 8-12.5 mg/m² once a week) according to the definition of improvement will be randomised to receive either medium dose parenteral methotrexate (SC or IM 15 mg/m² once a week, max dose 20 mg a week) in the randomised phase of the trial
 - b. Patients must be on a stable dose of no more than one Non-Steroidal Anti-Inflammatory Drugs (NSAID) for at least one month before the randomised period, and during the trial
 - c. Low dose steroids (0.2 mg/kg/day [max 10 mg/day]), if administered, will be maintained below 0.2 mg/kg/day (max 10 mg/day) one month before enrolment in the randomisation phase, and throughout the trial
 - d. Females of child bearing potential must have a negative pregnancy test at the beginning of the trial. If sexually active, they must agree to use adequate contraception (i.e. oral contraceptive, diaphragm with spermicidal cream, or Intra-Uterine Device [IUD]), throughout study participation, and must have no intention of conceiving a child during the course of the study.
 - e. Ability of the patients and/or parents to communicate meaningfully with the investigational staff, and competence to give written informed consent and/or assent, and ability to comply with the entire study procedures is essential
 - f. Duly executed, written, informed consent from patients (if 18 years of age or older) or parents or other legal guardian or representative (if less than 18 years of age), and assent obtained from the patient (aged 12-18 years when appropriate)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2003

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Molecular Pathology

London

United Kingdom

W1T 4JF

Sponsor information

Organisation

Arthritis Research Campaign (ARC) (UK)

ROR

<https://ror.org/02jkpm469>

Funder(s)

Funder type

Charity

Funder Name

Arthritis Research Campaign (UK)

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	safety and efficacy results	01/04/2010		Yes	No
Results article	results	01/08/2010		Yes	No
Results article	results	07/09/2010		Yes	No