ISRCTN59862338 https://doi.org/10.1186/ISRCTN59862338

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

Registration date
06/01/2003

Overall study status
Completed

Last Edited
03/11/2011

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled 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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

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 - href=¿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/m^2 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/m^2 once a week) according to the definition of improvement will be randomised to receive either medium dose parenteral methotrexate (SC or IM 15 mg/m^2 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

Age group
Other

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Department of Molecular Pathology
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Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

Sponsor details

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info@arc.org.uk

Sponsor type
Charity

Website
http://www.arc.org.uk

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (UK)

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	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