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Use of dried blood spots to measure methotrexate levels and its polyglutamates as biomarkers of methotrexate use in paediatric patients with Juvenile Idiopathic Arthritis (JIA) and Juvenile Dermatomyositis (JDM)

Submission date
20/10/2011

Recruitment status
No longer recruiting

Registration date
02/12/2011

Overall study status
Completed

Last Edited
26/10/2015

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Methotrexate is an important drug in treating children with rheumatic disorders such as juvenile idiopathic arthritis (joint inflammation) and juvenile dermatomyositis (skin rash and muscle inflammation). Finger prick dried blood spot samples is the technique widely used in newborns for diagnosing diseases at birth. It requires collection of a few drops of blood on a card which can then be posted to a central laboratory and is very well established. We aim to develop a method for determining methotrexate levels in dried blood spot samples. This method could be used to determine patients have difficulties in absorbing methotrexate, their response to long-term methotrexate treatment, their adherence with prescribed treatment. Dried blood spot sampling is easy to perform and requires very small volumes of blood (a few drops of blood from a simple finger prick), potentially allowing parents to take samples at home, for example, to assist in the monitoring of their child. In addition, such samples are easy to store and transport, without special conditions. The method will also facilitate more research with methotrexate, which will benefit future patients.

Who can participate?
Children aged 4-16 years diagnosed with either juvenile idiopathic arthritis or juvenile dermatomyositis and prescribed methotrexate for at least 2 months.

What does the study involve?
Not provided at time of registration.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
The Royal Liverpool Children's Hospital (Liverpool), Musgrave Park Hospital (Belfast) and the University College London (UCL) Institute of Child Health / Great Ormond Street Hospital for Children (GOSH) (London) (UK).

When is study starting and how long is it expected to run for?
April 2011 to April 2012.

Who is funding the study?
Arthritis Research UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11019

Study information

Scientific Title
Use of dried blood spots to measure methotrexate levels and its polyglutamates as biomarkers of methotrexate use in paediatric patients with Juvenile Idiopathic Arthritis (JIA) and Juvenile Dermatomyositis (JDM): an observational study

Study objectives
Use of dried blood spots to measure methotrexate and its polyglutamates as biomarkers of methotrexate use in paediatric patients with Juvenile Idiopathic Arthritis (JIA) and Juvenile Dermatomyositis (JDM).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office of Research Ethics Committees of Northern Ireland, First MREC approval date 01/10/2011, ref: 10/NIR03/33

Study design
Non-randomised observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Juvenile Idiopathic Arthritis (JIA), Juvenile Dermatomyositis (JDM)

Interventions
We will test the possibility of developing an analytical method for the determination of methotrexate and its polyglutamate metabolites in dried blood spot samples. We will also be examining the practicality of home sampling in children.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To determine the possibility of developing an analytical method for the determination of methotrexate and its polyglutamate metabolites in dried blood spot samples

Secondary outcome measures

To determine whether home sampling is practical

Overall study start date
01/04/2011

Completion date
01/04/2012

Eligibility

Key inclusion criteria
1. Children aged 4-16 years diagnosed with either juvenile idiopathic arthritis or juvenile dermatomyositis (confirmed by a consultant) attending the rheumatology clinic at the paediatric rheumatology outpatient clinics at three sites: the Royal Liverpool Children's Hospital (Liverpool), Musgrave Park Hospital (Belfast) and the University College London (UCL) Institute of Child Health / Great Ormond Street Hospital for Children (GOSH) (London)
2. The child is prescribed methotrexate for at least 2 months (oral or subcutaneous)

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
Do not meet the above inclusion criteria or if patients (or their parents/ guardians) do not wish to particpate in the research

Date of first enrolment
01/04/2011

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
The Queen's University of Belfast
Belfast
United Kingdom
BT7 1NN

Sponsor information

Organisation
Arthritis Research UK (UK)

Sponsor details
ARC Epidemiology Unit
The Queen's University of Belfast
University Road
Belfast
United Kingdom
BT97 1NN

Sponsor type
Charity

Website
http://www.arthritisresearchuk.org/

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	22/10/2015		Yes	No
HRA research summary			28/06/2023	No	No