# 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	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
20/10/2011		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
02/12/2011	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
26/10/2015	Musculoskeletal Diseases			

#### 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? Abdel Qader Al Bawab aalbawab02@qub.ac.uk

## Contact information

## Type(s)

Scientific

#### Contact name

Mr Abdel Qader Al Bawab

#### Contact details

Main Campus University Road Belfast United Kingdom **BT7 1NN** 

aalbawab02@qub.ac.uk

## 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