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# Steroid induction regimen for juvenile idiopathic arthritis

**Submission date**
26/01/2016

**Recruitment status**
No longer recruiting

**Registration date**
03/02/2016

**Overall study status**
Completed

**Last Edited**
10/08/2020

**Condition category**
Musculoskeletal Diseases

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

## Plain English summary of protocol

Background and study aims
JIA stands for Juvenile Idiopathic Arthritis. Arthritis means inflammation in the joints leading to pain, stiffness, swelling and warmth. It can cause damage and reduced movement in the affected joints. The term JIA covers several types of arthritis that start under the age of 17 and for which there is no known cause. It is a chronic disease, meaning that it can cause trouble for many years. About half of the patients will continue to suffer from arthritis as adults. There are many good treatments for JIA including anti-inflammatory drugs, disease modifying drugs, and new 'biologic' drugs. They block the inflammation. Although these newer drugs are good, they are powerful and expensive and sometimes not effective enough. Patients often still need steroids at the start of treatment and if it flares up again. A short course can stop the flare and reduce the increases in other treatments. There are four ways that steroids are given: by injection into joints (intra-articular), injection through a drip into veins (intra-venous), injections into the muscle (intramuscular depot) or by tablets taken by mouth (oral). These have all been used for decades but without studies to compare them. There is currently no agreement about the best way to give steroids for JIA and for how long. Steroids are used in many studies of new biologic drugs but so far there has been only one study comparing two different steroid preparations in joint injections. It is important to know how best to use steroids as they can have many side effects. They can cause weight gain, reduced growth, increased risk of diabetes, high blood pressure and weakened bones. It is important to work out the lowest dose and best way to give them for the shortest time. The aim of this study is to identify the best steroid treatments to compare, what outcomes to measure, and whether people would be willing to participate in a future study.

Who can participate?
Patients aged under 16 with JIA and their parents/carers

What does the study involve?
A thorough search of the published research on steroids in JIA is performed to identify important clinical outcomes. A UK-wide study of practice is conducted to see what HCPs do currently. A national survey of HCPs is carried out to identify current treatments in different scenarios and what affects the decision to choose a specific treatment. Patients and parents are interviewed to develop the design of a future study comparing steroids and their delivery routes

and to identify important outcomes, as well as their thoughts on whether they would take part in such a study. We also conduct a small study of the type of patients we think would take part in a future study receiving the proposed steroid treatments while observing any changes in the agreed outcome measures over a 3-month period, so that we can calculate how many patients would be needed for a future study.

What are the possible benefits and risks of participating?
All participants (parents as well as healthcare professionals) completing the study will be provided with a certificate to acknowledge their contribution to the research. The only anticipated risk of the study is that a patient/parent may become distressed during the interviews if sensitive/distressing topics are discussed. The interviews will be conducted by researchers who are highly experienced within this field, and an additional contact number will be available after the interview if required.

Where is the study run from?
Alder Hey Childrens Foundation NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2016 to March 2019

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Eileen Baildam

# Contact information

### Type(s)
Scientific

### Contact name
Dr Eileen Baildam

### ORCID ID
http://orcid.org/0000-0001-8463-6388

### Contact details
Alder Hey Children’s Foundation NHS Trust
Alder Hey Hospital
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L12 2AP

# Additional identifiers

### EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
HTA 14/167/01

# Study information

**Scientific Title**
Steroid induction regimen for juvenile idiopathic arthritis (SIRJIA): a multicentre feasibility trial

**Acronym**
SIRJIA

**Study objectives**
Juvenile idiopathic arthritis (JIA) is an autoimmune, non-infective, inflammatory joint disease affecting children and adolescents. This feasibility study is being conducted to determine whether it is possible to conduct a future randomised controlled trial to assess steroid treatment regimens in JIA.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/1416701

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
North East - Newcastle and North Tyneside REC, 18/03/2016, ref: 16/NE/0047

**Study design**
Multicentre feasibility trial

**Primary study design**
Observational

**Secondary study design**
Feasibility trial

**Study setting(s)**
Hospital

**Study type(s)**
Other

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

**Health condition(s) or problem(s) studied**
Juvenile idiopathic arthritis

### Interventions
The trial will comprise of a literature review, a prospective study to collect observational data (to inform a possible future RCT), a survey of healthcare professionals on current practice, qualitative interviews and a Delphi process with consensus stakeholder meeting.

1. National e-Survey: UK HCPs in both specialist children s centres and DGHs with paediatric rheumatology clinics, identified through BSPAR, will be surveyed on current practice, reasons for treatment choices and capability/ acceptability of undertaking a trial, numbers of patients and type of JIA and CS use.
2. A qualitative study of patients and parents (identified by units) will probe acceptability of treatment routes, willingness to be randomised and provide consent, trial design and outcomes, feeding into the Delphi and final study report.
3. Delphi Process: UK-wide HCPs with parents/patients will be invited to participate in a two-round Delphi process to achieve consensus on the primary outcome measure
5. Consensus Meeting: HCPs & parents/patients to finalise agreement on key aspects of proposed RCT including patient groups, primary outcome, control and treatment arms
6. Prospective feasibility study including data on chosen primary outcome collected at 3 months to inform estimate of sample size for future RCT
7. Report on feasibility of proposed RCT project

### Intervention Type
Mixed

### Primary outcome measure
Develop outcomes of the feasibility study including a report to HTA with assessment of the proposed intervention and control arms for definitive study

### Secondary outcome measures
1. A comprehensive assessment of current UK practice as regards JIA CS treatment, and potential trial capability and acceptability (by conducting a national survey)
2. Ascertainment of HCP views on the most appropriate patient group(s) and control and intervention arms (through a stakeholder consensus meeting)
3. A qualitative study of parent and patient perspectives in relation to a future RCT of CS
4. The choice of a primary outcome measure for a clinical trial in children and young people with JIA (through literature review, Delphi process and stakeholder consensus meeting)
5. Undertake a prospective feasibility study for the early induction of remission in children and young people with JIA testing chosen primary outcome, treatment arms and JIA subgroups to be studied

### Overall study start date
01/01/2016

### Completion date
31/03/2019

## Eligibility

### Key inclusion criteria
Patients with JIA and their parents/carers will be eligible to take part in the qualitative research aspect of the trial

**Participant type(s)**
Mixed

**Age group**
Mixed

**Sex**
Both

**Target number of participants**
It is anticipated that 16 families will provide sufficient data for the qualitative research element

**Total final enrolment**
297

**Key exclusion criteria**
Patients aged under 8 years and patients/carers residing more that one days' travel away from the primary research site (Liverpool)

**Date of first enrolment**
20/06/2018

**Date of final enrolment**
20/09/2018

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Alder Hey Childrens Foundation NHS Trust**
Liverpool
United Kingdom
L12 2AP

# Sponsor information

**Organisation**
Alder Hey Children’s Foundation NHS Trust (UK)

**Sponsor details**

Eaton Road
West Derby
Liverpool
England
United Kingdom
L12 2AP

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/00p18zw56

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
The aim of this study is to establish the feasibility of a future RCT of different steroid induction regimens in children with JIA. The key output will be a report to the HTA which includes detailed data on key parameters for a proposed RCT which will enable a recommendation on its feasibility. Therefore it is anticipated that a major focus will be a dissemination strategy for national 'buy-in' from HCPs and children with JIA in preparation for a definitive trial based on the findings of the feasibility study. The Trial Steering Group will lead this, ensuring that multi-disciplinary/sector requirements are considered. This will be supported by the chosen feasibility methodologies, which encourage co-construction and stakeholder engagement from the outset. The applicants have the necessary profile and influence within relevant national committees to

ensure that this dissemination strategy will be effective, irrespective of the lead investigators for a future RCT. In addition, the feasibility study will produce a number of discrete outputs, which will require dissemination to relevant stakeholders through multi-modal media:

1. Survey of practice among UK paediatric rheumatologists in an era of biologic therapies: these data will be published independently and contribute to the wealth of literature in this area. We will report on current clinical practice in the UK and the relative importance of outcomes to consumers and to providers of care.
2. Delphi and consensus findings: In addition the report of the Delphi process in agreeing a protocol in a complex multidimensional treatment area will be published as of interest even as a standalone finding, and in turn develop into the proposal for the full RCT for publication. This will also be proactively disseminated through BSPAR, the CSG, and through the international paediatric rheumatology community from the teams established leadership roles with these.
3. Report on the PPI involvement in this detailed feasibility study - will be an important output for other consumers involved in research. This will be disseminated within NIHR CRN through leadership from the PPI co-applicants and consumer group.

The overarching methods and outputs of this feasibility study will also be presented at relevant national meetings including the BSPAR national annual meeting, the BSR national annual conference and the RCPCH annual meeting. It will also be submitted for publication in peer-reviewed journals.

## Intention to publish date
31/03/2019

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the study is a feasibility pilot and patients are not consented to share their data as a dataset nationally. However, the findings will inform a future full trial when the trialists can recommend that this sort of specific consent is included. Any requests for data would be considered on an individual basis by the Trial Management Group. The qualitative interview data is not suitable for dataset release by virtue of the nature of qualitative research where themes are sought from transcripts of the personal interviews.

## IPD sharing plan summary
Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/07/2020 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |