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Steroid Treatment Trial in JIA (STAR-JIA): A randomised trial to compare the effectiveness, safety and cost-effectiveness of intravenous versus oral corticosteroid induction regimens for children and young people with juvenile idiopathic arthritis

Submission date
15/07/2023

Recruitment status
Recruiting

Registration date
08/09/2023

Overall study status
Ongoing

Last Edited
04/02/2026

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to compare two different steroid treatments in children and young people with new-onset polyarticular juvenile idiopathic arthritis (JIA) to find out which is best. Medications used in the long-term management of JIA take around 12 weeks to start working. Steroids act quickly, reducing inflammation whilst the other medications start to work but have many potential side effects. There is a lack of evidence to suggest whether intravenous steroids or oral steroids are more effective, safe, tolerable for patients and which have a greater impact on quality of life.

Who can participate?
Patients aged 1-18 years of age with at least five inflamed joints and newly diagnosed polyarticular JIA

What does the study involve?
They will be randomly allocated to either a 6-week course (reducing dose regimen) of prednisolone liquid or tablets, taken at home OR a 3-day course of intravenous methylprednisolone on a hospital day-case unit. Participants will be assessed before starting treatment (baseline) and four follow-up visits at 6, 12, 24 and 52 weeks, in line with standard care appointments. Study visits will include assessments in standard care however, additional study-specific assessments will include reporting of side effects, and steroid toxicity risk including extra blood tests, questionnaires relating to the impact of JIA and treatment on quality of life and cost. The study offers an option for participants to donate blood samples for storage in a biobank for future research. Samples will not be analysed as part of the study but adopted by Liverpool University Biobank.

What are the possible benefits and risks of participating?
The direct burden on participation will be minimal as all research visits have been scheduled at the same time as standard-of-care visits to minimise the burden to participants. Research blood samples are taken at the same time as standard-of-care bloods to reduce burden.
Participants will be asked to complete several questionnaires which will prolong their clinic appointments. Once complete the questionnaire will be handed to the research team.
Risks associated with being treated with steroids (the IMP and the comparator) via different routes for JIA with the IMP, These risks are stated in the trial information sheets and site teams are appropriately trained as both routes of administration are used as standard of care.
All of the above risks are minimized with appropriate training and following policies and procedures by hospital Trusts and as stated in the protocol. For participants receiving oral prednisolone from hospital pharmacies, the pharmacy will dispense the drug as prescribed with appropriate guidance for taking it. For participants receiving IV methylprednisolone over 3 days on a hospital day unit, nurses who normally work on the day unit and have been appropriately trained to give IV methylprednisolone will be responsible for administering the drug and monitoring participants. It will not be given by Research Nurses who may be less familiar with the administration of this drug and do not usually administer this drug. This will minimize the risk of drug preparation, administration and monitoring errors.

Where is the study run from?
Alder Hey Children's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2023 to July 2028

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

Who is the main contact?
star-jia@liverpool.ac.uk

Contact information

Type(s)
Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
1007610

Central Portfolio Management System (CPMS)
58347

Protocol serial number
AH23-05-006

Study information

Scientific Title
Steroid Treatment Trial in JIA (STAR-JIA): A randomised trial to compare the effectiveness, safety and cost-effectiveness of intravenous versus oral corticosteroid induction regimens for children and young people with juvenile idiopathic arthritis

Acronym
STAR-JIA

Study objectives
Primary objectives:
To compare the clinical effectiveness of intravenous methylprednisolone versus oral prednisolone for controlling new-onset polyarticular juvenile idiopathic arthritis (JIA) in JIA Core Outcomes.

Secondary objectives:
1. To compare the differences in JIA Core Outcomes for intravenous methylprednisolone versus oral prednisolone for the following domains:
1.1. Pain
1.2. Function

1.3. Health-related Quality of Life (HRQOL)
2. To assess the effectiveness of intravenous versus oral corticosteroids in minimising the need for additional treatments including all corticosteroid routes and additional disease-modifying anti-rheumatic drugs (DMARDs)/biologics.
3. To evaluate short/medium-term safety and tolerability of IV versus oral corticosteroids, with regards to adverse reactions, serious adverse events, laboratory assessments and paediatric glucocorticoid toxicity index (pGTI).
4. To determine if a dose-response relationship can be identified in the efficacy/adverse responses to corticosteroids across all participants by secondary analysis, normalising corticosteroids received for dose, bioavailability and potency using previously published data.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/09/2023, Yorkshire and the Humber - Leeds East (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle-upon-Tyne, NE2 4NQ, United Kingdom; +44 (0)207 1048171, (0) 207 104 8141; leedseast.rec@hra.nhs.uk), ref: 23/YH/0173

Primary study design
Interventional

Study design
Open randomized controlled parallel-group trial

Study type(s)
Efficacy, Safety, Treatment

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

Interventions
IMP: Intravenous methylprednisolone administered over 3 days on a hospital day unit
Comparator: Oral prednisolone taken/administered over 6 weeks at home

The doses, frequency and method of administration of the IMP and comparator drug are provided below.

IMP: Methylprednisolone
Route: Intravenous administration
Form: Powder for injection to be prepared for intravenous administration
30 mg/kg per day for 3 consecutive days (Maximum dose: 1g per day)

Comparator: Prednisolone
Route: Oral administration
Form: Tablet or solution
The initial dose of prednisolone will be 1 mg/kg per day with a maximum dose of 40 mg. For participants weighing ≥40 kg, the weaning will be a reduction in line with the percentage decrease used for lighter patients.

Week of oral prednisolone 1: Dose (patient <40 kg): 1 mg/kg per day; Dose (patient ≥40 kg): 40 mg
Week of oral prednisolone 2: Dose (patient <40 kg): 0.75 mg/kg per day; Dose (patient ≥40 kg): 30 mg
Week of oral prednisolone 3: Dose (patient <40 kg): 0.5 mg/kg per day; Dose (patient ≥40 kg): 20 mg
Week of oral prednisolone 4: Dose (patient <40 kg): 0.375 mg/kg per day; Dose (patient ≥40 kg): 15 mg
Week of oral prednisolone 5: Dose (patient <40 kg): 0.25 mg/kg per day; Dose (patient ≥40 kg): 10 mg
Week of oral prednisolone 6: Dose (patient <40 kg): 0.125 mg/kg per day; Dose (patient ≥40 kg): 5 mg

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Methylprednisolone, prednisolone

Primary outcome(s)
Primary clinical outcome:
Disease activity measured using the JADAS10 score at 0 weeks (Baseline) and 6 weeks

Primary economic outcomes:
1. Incremental cost per quality-adjusted life year (QALY) gained measured using Resource Use Questionnaires and Patient Level Information and Costing System (PLICS) data at 0 weeks (Baseline), 6 weeks, 12 weeks, 24 weeks and 52 weeks.
2. Resource use, costs and health utilities associated with IV and oral corticosteroids measured using Resource Use Questionnaires and Patient Level Information and Costing System (PLICS) data at 0 weeks (Baseline), 6 weeks, 12 weeks, 24 weeks and 52 weeks.

Key secondary outcome(s)
1. Disease activity in subjects with polyarticular Juvenile Idiopathic Arthritis (JIA) randomised to IV methylprednisolone or oral prednisolone measured using the American College of Rheumatology (ACR) Pediatric Response Criteria (30, 50, 70, 90, 100) at 0 weeks (baseline), 6 weeks, 12 weeks, 24 weeks, 52 weeks.
2. Disease activity in subjects with polyarticular Juvenile Idiopathic Arthritis (JIA), randomised to IV methylprednisolone or oral prednisolone measured using the JADAS (10,27,71) at 0 weeks (baseline), 6 weeks, 12 weeks, 24 weeks, 52 weeks.
3. Disease activity in subjects with polyarticular Juvenile Idiopathic Arthritis (JIA) randomised to IV methylprednisolone or oral prednisolone measured by JADAS10 cut-off scores at 0 weeks (baseline), 6 weeks, 12 weeks, 24 weeks, 52 weeks.
4. Pain in subjects with polyarticular Juvenile Idiopathic Arthritis (JIA) randomised to IV methylprednisolone or oral prednisolone measured using the Pain Visual Analogue Scale (Pain VAS) at 0 weeks (baseline), 6 weeks, 12 weeks, 24 weeks, 52 weeks.
5. Function in subjects with polyarticular Juvenile Idiopathic Arthritis (JIA) randomised to IV methylprednisolone or oral prednisolone measured using the Childhood Health Assessment

Questionnaire (CHAQ) at 0 weeks (baseline), 6 weeks, 12 weeks, 24 weeks, 52 weeks.
6. Health-related Quality of Life (HRQoL) in subjects with polyarticular Juvenile Idiopathic Arthritis (JIA) randomised to IV methylprednisolone or oral prednisolone measured using Child Health Utility 9D Questionnaire (CHU-9D) and CAPTURE-JIA PROM at 0 weeks (baseline), 6 weeks, 12 weeks, 24 weeks, 52 weeks.
7. Requirement for additional treatment for subjects with polyarticular Juvenile Idiopathic Arthritis (JIA) due to failure to respond to IV methylprednisolone or oral prednisolone measured using concomitant medications recorded at 6 weeks, 12 weeks, 24 weeks, 52 weeks.
8. Glucocorticoid toxicity in subjects with polyarticular Juvenile Idiopathic Arthritis (JIA) randomised to IV methylprednisolone or oral prednisolone measured using Paediatric Glucocorticoid Toxicity Index (pGTI) scores at 0 weeks (baseline), 6 weeks, 12 weeks, 24 weeks, 52 weeks

Completion date
31/07/2028

Eligibility

Key inclusion criteria
1. Participants must be between 1-18 years of age inclusive
2. New onset pcJIA diagnosed by a paediatric rheumatologist (to include polyarticular rheumatoid factor (RF+) positive, polyarticular RF negative, enthesitis-related arthritis, psoriatic arthritis and extended oligo-articular). This includes new diagnosis of JIA with at least 5 joints affected and patients previously categorised as oligoarticular JIA (with 4 joints or less) who have extended to at least 5 joints.
3. Participants are expected to be able to commence allocated treatment within 1 week of randomisation
4. Written, informed consent and where appropriate, assent obtained from participant or their legal representative
5. Participants of child-bearing potential must be willing to abstain from sexual intercourse from consent to their final visit and/or use another acceptable contraception method as described in section 9.10.5 of this protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
1 Years

Upper age limit
18 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Any contraindication to starting corticosteroids
2. Any contraindication to starting methotrexate
3. Pregnancy
4. Treatment with systemic corticosteroids within 4 weeks preceding screening (includes IV, IA, IM and oral)
5. Treatment with methotrexate within 12 weeks preceding screening
6. Any co-morbidity which in view of the treating clinician makes participation inappropriate

Date of first enrolment
05/03/2024

Date of final enrolment
06/02/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Wales

Study participating centre
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
England
L12 2AP

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Study participating centre

University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
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England
BS1 3NU

Study participating centre
University Hospitals Sussex NHS Foundation Trust
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BN11 2DH

Study participating centre
Noahs Ark Childrens Hospital for Wales
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Study participating centre
John Radcliffe Hospital
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Royal Preston Hospital
Sharoe Green Lane
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PR2 9HT

Study participating centre

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Freeman Road
High Heaton
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NE7 7DN

Study participating centre
New Cross Hospital
Wolverhampton Road
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WV10 0QP

Study participating centre
Bradford Royal Infirmary
Chesnut House
Duckworth Lane
Bradford
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BD9 6RJ

Study participating centre
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Newcastle Road
Stoke-on-trent
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ST4 6QG

Study participating centre
Manchester Royal Infirmary
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M13 9WL

Study participating centre
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WC1N 3JH

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S5 7AU

Study participating centre
Addenbrooke's Hospital
Hills Road
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CB2 0QQ

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Sandford Road
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GL53 7AN

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Study participating centre
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Study participating centre
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LE1 5WW

Sponsor information

Organisation
Alder Hey Children's NHS Foundation Trust

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be made available on request from Liverpool Clinical Trials Centre, star-jia@liverpool.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes