MANCHESTER 1824
The University of Manchester

British Society for Rheumatology

VERSUS ARTHRITIS

UK JIA Biologics Register Newsletter

Summer 2024

Monitoring long-term safety of treatments for JIA over two decades

Professor Taunton Southwood was the first Chief Investigator of the BSPAR Etanercept Study, which was established at the University of Birmingham in 2004.

"The UK JIA Biologics Register is the one of the most important and productive collaborative research resources in the field of paediatric rheumatology created during my career. I am honoured to have shared in its formation and successful implementation with so many of my colleagues"

"It will undoubtedly continue to have a major impact in our efforts to improve the health of children for many years into the future."

The BSPAR Etanercept Study moved to the University of Manchester in 2010, to join the Biologics for Children with Rheumatic Diseases (BCRD) study, led by Professor Kimme Hyrich.

The two studies together created the **UK JIA Biologics Register**, which continues to recruit and collect follow-up data from children and young people with JIA.

Thank you for your involvement in the studies over the last 20 years, it is very much appreciated!

Highlighted discoveries

Professor Kimme Hyrich and Dr Lianne Kearsley-Fleet, University of Manchester, are Co-CIs of the UK JIA Biologics Register. They reflect on the important discoveries over the last two decades:

Switching biologics: "We found that in those where their first biologic (a TNF inhibitor) didn't work, patients responded equally well whether they started a second TNF inhibitor, or switched to a different class of biologic therapy".

Uveitis: "We have shown that there was no increased risk of developing uveitis in those treated with etanercept when compared with methotrexate".

Growth: "We found that patients starting Enbrel were shorter than people who did not have JIA. However, the height of patients with JIA significantly improved after two years of treatment, suggesting that the control of inflammation can help with growth in some children".

Remission: "We have found that one-in-five patients on biologic therapy stopped for remission after approximately 2 years of treatment".

All publications can be found at the bottom of this webpage: https://sites.manchester.ac.uk/bcrdbspar/

LATEST RESEARCH

Dr Lianne Kearsley-Fleet *asked the question....*

"What are the outcomes for children and young people with JIA who switch from an originator to a biosimilar?"

What is already known?

Biologic therapies are one of the main treatment options for children and young people with juvenile idiopathic arthritis (JIA). Over time, the patents for the original drugs have started to expire in Europe, and consequently other pharmaceutical companies have been able to make the drug; known as biosimilars. Biosimilar therapies must demonstrate in clinical trials that they work the same as the originator therapy. However, these trials are often done in conditions in adults (such as rheumatoid arthritis) rather than in children and young people with JIA. Due to the competitive pricing of biosimilar therapies, many children and young people with JIA are being switched from an originator therapy onto the biosimilar product. This is termed a 'non-medical switch' (i.e. not for ineffectiveness or an adverse event).

What data were used?

164 children and young people with JIA who swapped from an originator (the original) onto the biosimilar (of the same product)

Compared outcomes with

A matched cohort of children and young people with JIA who did not switch, and instead remained on the original.

What was discovered?

Those who swapped treatments (onto the biosimilar) appeared to do just as well compared with those who remained on the original.

- Children had similar disease activity after six months (regardless of whether they switched or not).
- Most children were still receiving their biosimilar after one year (a sign they are doing well on treatment).
- Switching back to the originator was uncommon (fewer than one-in-ten by one year).

Why is this important / what is the benefit?

This is one of the largest analyses of children and young people with JIA showing that those who switch from an originator to a biosimilar product appear to do just as well with regards to how long they remain on treatment for (a sign they are doing well on treatment) and also how well their arthritis is, compared with those who remained on the originator.

This information is reassuring to clinicians, children and families regarding the impact of non-medical biological switching. The data suggest good tolerance of non-medical switching in this population.

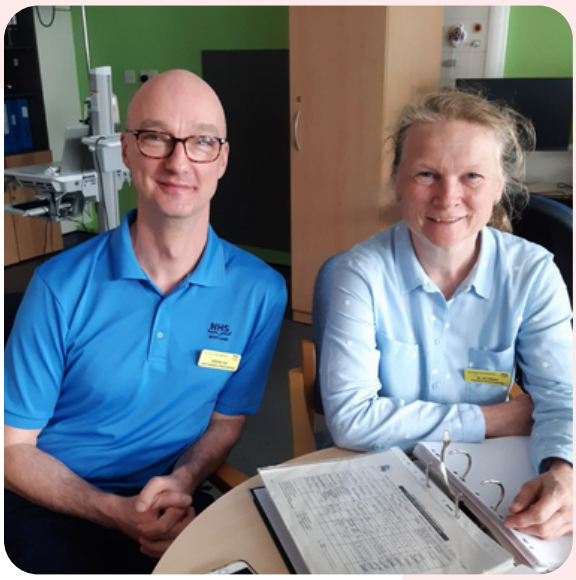
https://doi.org/10.1016/s2665-9913(24)00087-0

Associate PI scheme

We are delighted to welcome our first applicant on to the Associate Principal Investigator (API) scheme. Drew Fell works at the Royal Hospital for Children in Glasgow and is completing the scheme under the guidance of PI, Dr Jo Walsh.

The Associate PI (API) scheme aims to develop doctors, nurses and other health professionals to become the Principal Investigators (PIs) of the future via a six-month programme, covering all aspects of the study. The Local PI mentors and supports the API as they learn about the delivery of research and complete the API Scheme checklist of activities.

If you can identify someone at your site who would be interested in an API role please let us know, and we would be happy to support you!



Mr Drew Fell and Dr Jo Walsh, reviewing the study site file as part of an API module

More information can be found here:
https://www.nihr.ac.uk/health-and-care-professionals/training/associate-principal-investigator-scheme.htm

Recruitment Reminders

Eligibility:

- Diagnosis of Juvenile Idiopathic Arthritis.
- Under 18 years of age.
- Starting treatment with a biologic, biosimilar or JAK inhibitor.
- Willing to provide consent (within six months of treatment start date for new patients, within 2 years for re-registrations).

Funding:

- Please remember: due to a revision of the funding model, we are now able to offer payments for ALL data submitted to the UK JIA Biologics Register (£50 per form, conditions apply).
- Up to £350 is available for each tofacitinib participant recruited.

Participants with JIA who are starting treatment with tofacitinib can be registered with the BCRD Study!

This includes people who were previously registered on either the BCRD or BSPAR study, as well as those who have never been registered before.

BCRD or BSPAR Study participant (under 18 years old) switches treatment to tofacitinib

01. If already registered on BCRD, approach participant for re-consent in BCRD and complete new baseline. They can be re-consented up to 2 years after starting treatment with tofacitinib

02. If already registered on BSPAR, approach participant for consent for BCRD and complete new baseline. They can be re-consented up to 2 years after starting treatment with tofacitinib

03. Ensure final follow up forms for original Study ID are completed. Follow-up under this ID number will now cease.

04. Follow-up period begins again under the new Study ID number.

05. All forms submitted under the new Study ID number are eligible for a payment of £50 (up to 5 years of follow-up).

UK JIA Biologics Register

Please contact praksha.Jariwala@manchester.ac.uk if you need any assistance with the studies