

Resource

British Society for Rheumatology Biologics Register – RA

The BSRBR-RA study tracks the progress of people with rheumatoid arthritis (RA) who have been prescribed biologic (including biosimilar) and other targeted therapies in the UK to monitor the long-term safety of these drugs.

[Print](#)

What is the study about?

The BSRBR-RA is one of the largest prospective studies of patients receiving these drugs in the world, with over 20,000 patients registered in the study since it started in 2001.

This epidemiological study is a unique collaboration between The University of Manchester, the British Society for Rheumatology and the pharmaceutical industry. All consultant rheumatologists in the UK who have prescribed anti-TNF, and other targeted therapies, have an opportunity to participate in the register, supported by allied health professionals.

The Register captures data from rheumatologists and nurses who are looking after patients with RA, as well as asking patients themselves to complete questionnaires on how they are feeling. We also receive clinical data from national NHS databases (including NHS Digital) to enhance the data we collect.

Why is the BSRBR-RA so important?

When we start a new drug, we often ask ourselves if it is the right drug for me and will it cause me any harm or side effects. When most drugs are first approved for use, we actually have quite limited information on their safety. There will have been studies in animals to look at this, but these studies have their limitations as results can be different in humans. Most drugs will also undergo clinical trials, where their benefits and safety are also assessed, but sometimes these studies can be too small to detect rare safety problems and not all patients will be allowed to take part. Therefore, it is important that even after a drug can be prescribed by doctors we continue to monitor groups of patients receiving the drug for any unexpected harm. The BSRBR-RA has been set up specifically with this purpose and we have now followed over 30,000 patients receiving various biologic and other medications. Overall the results have been very reassuring but we must continue this effort as new drugs become available

Conventional Synthetic Disease Modifying Anti-Rheumatic Drug (csDMARD) Cohort

When biologic drugs were first available they represented a new option compared to conventional DMARDs such as methotrexate or sulphasalazine. Therefore when we set up the BSRBR-RA to look at side effects of biologics, we needed to know if these would be different to what we already knew about conventional DMARDs. Therefore, between 2001 and 2007 we recruited almost 4000 people receiving csDMARDs who had never received biologics. Many of our studies compare the rates of side effects or new health problems in people receiving biologics to people who are not. More recently, as more and more biologics become available, we undertake comparisons between different biologics types also



The registry team at Manchester

Examples of research published by the BSRBR-RA team

If you would like to read more, click on the underlined words.

- There is an expanding choice of biologic therapies available in the UK but not all people will respond to treatment. To understand the extent of refractory rheumatoid arthritis (disease that does not respond to biologic therapy) the BSRBR-RA has looked at the data to find out [which people might have refractory disease](#) to help guide rheumatology care in the future.
- People with rheumatoid arthritis won't necessarily have high levels of disease activity when measured by their rheumatology team at the hospital but will still have inflammation and pain and are classed as those with "moderate" disease. Currently in the UK, these people don't have access to biologic therapies. We looked at [data in people with moderate disease in the BSRBR-RA](#) to explore this further.
- A common question we receive is what is the risk of developing a serious infection after failing a

- first biologic and starting a second? In the BSRBR-RA we were able to look at the [risk of serious infections in patients after stopping their first TNF inhibitor drug and starting either a second TNF inhibitor or Mabthera \(rituximab\)](#).
- We looked in the BSRBR-RA data to see if people with rheumatoid arthritis [starting TNF inhibitors were at a higher risk of developing dementia compared to people receiving standard DMARD therapy](#).
 - We used the BSRBR-RA data to find out [which people with rheumatoid arthritis were most likely to benefit from Mabthera \(rituximab\)](#)
 - People with rheumatoid arthritis are at a higher risk of developing lymphoma (a blood cancer) but little is known about the effect of TNF inhibitors on this risk. We used BSRBR-RA data to look at the [risk of lymphoma in people on TNF inhibitors and people on standard DMARD therapy such as methotrexate](#)
 - Another treatment option for people with rheumatoid arthritis is RoActemra (tocilizumab). We looked at the BSRBR-RA data to find out [how well people responded to RoActemra depending on whether they had previously received a biologic drug in the past compared to those who hadn't](#).
 - People with rheumatoid arthritis are at increased risk of heart attacks (or myocardial infarction; MI) compared to the general population. The BSRBR-RA team wanted to [understand what the effect of TNF inhibitors was on the risk of heart attacks](#).
 - We have previously published data on the effect of TNF inhibitors in women with rheumatoid arthritis but little is known about [the effect of Mabthera \(rituximab\) in pregnancy](#). We used BSRBR-RA data to study this
 - A few rare syndromes (lupus-like and vasculitis-like syndromes) can affect people with rheumatoid arthritis. One of our researchers was particularly interested in finding out [how often these types of syndromes occurred and the effects of TNF inhibitors on these using the BSRBR-RA data](#)
 - BSRBR-RA researchers wanted to look at [different treatment options for people with rheumatoid arthritis who had previously had cancer to see if they were more likely to develop a new cancer](#)
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 - Juvenile Idiopathic Arthritis (JIA) is the most common type of arthritis that effects children and many continue to have disease as adults. As part of a PhD, one our researchers looked at [how adults with JIA responded to TNF inhibitor treatment](#)

Further lay summaries of BSRBR-RA studies can be found [here](#).

[Web link](#)

[Visit the BSRBR-RA study website](#)

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What Drugs are or have ever been included in the BSRBR-RA (as at December, 2020)

Should you wish to know if an advanced therapy you are on has had data collected by the Registry either now, or in the past, here is a list with both generic and brand names.

Drug (Generic/TRADENAME)

- Etanercept ENBREL
- Infliximab REMICADE
- Anakinra KINERET
- Adalimumab HUMIRA
- Rituximab MABTHERA
- Tocilizumab ROACTEMRA
- Certolizumab CIMZIA
- Infliximab INFLECTRA
- Infliximab REMSIMA
- Etanercept BENEPALI
- Infliximab FLIXABI
- Tofacitinib XELJANZ
- Sarilumab KEVZARA
- Baricitinib OLUMIANT
- Etanercept ERELZI
- Rituximab RIXATHON
- Adalimumab AMGEVITA

The BSRBR-RA is part of the [Biologic Studies Group](#), led by Professor Kimme Hyrich at the University of Manchester. There are a number of other studies within the group, studying the safety and efficacy of biologic, biosimilar and other targeted therapies in musculoskeletal and dermatological conditions.

- [British Society for Paediatric and Adolescent Rheumatology Etanercept Study \(BSPAR ETN\)](#)

This national UK study recruits a cohort of children with Juvenile Idiopathic Arthritis (JIA) who are starting etanercept, alongside a comparison group starting methotrexate. Originally established at the University of Birmingham in 2004, the BSPAR ETN study moved to the BSG in 2010 and now has over 2,000 registrations from 51 centres.

- [Biologics for Children with Rheumatic Diseases \(BCRD\)](#)

A sister study to the BSPAR-ETN, BCRD started in 2010 and recruits children with JIA starting treatment with biologic/biosimilar therapy (other than etanercept), alongside a comparison group of children starting methotrexate. Over 1,400 participants have been recruited from 38 centres

- [British Association of Dermatologists Biologics and Immunomodulators Register \(BADBIR\)](#)

Established in 2007, BADBIR is a long-term prospective observational cohort study monitoring the safety and efficacy of biologic therapy in people with severe psoriasis. BADBIR has over 19,500 registrations from 164 centres

- [British Isles Lupus Assessment Group Biologics Register \(BILAG-BR\)](#)

BILAG-BR is a national study looking at the long-term safety and efficacy of biologic therapy in patients with lupus, compared with a group receiving standard immunosuppressive therapy. Established in 2010, BILAG now has 1,300 registrations from 59 centres.

- [Childhood Arthritis Prospective Study \(CAPS\)](#)

CAPS recruits children who are newly diagnosed with juvenile idiopathic arthritis. It was established in 2001 and aims to discover ways to predict how patients will manage over the long term. 1,700 participants have been recruited from 7 centres across the UK

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