Newsletter for lupus patients taking part in the British Isles Lupus Assessment Group Biologics Register (short name - BILAG BR study)

Spring 2019

Welcome to the BILAG BR study newsletter. We send this to participants who are involved in this important research and aim to provide information on the study, updates on how things are going, what we have found out so far and what we hope to find out in the future.

What is the BILAG BR study?

We are proud to be one of the largest studies looking at the long term 'real world' safety and effectiveness of new drugs prescribed for lupus. Since 2010, we have registered **over 1000** people with lupus who have started treatment with a biologic therapy, biosimilar or non-biologic therapy.

We recruit people who are starting treatment with a **biologic therapy**, and then collect data at regular intervals to see how things are going. Alongside this group, we collect data from a **comparison group** of people with lupus who are receiving treatment with non-biologic therapy (such as azathioprine or mycophenolate mofetil) who have never received biologic treatment.

This data is then used to compare the **safety and effectiveness** of the treatments and see if there is any increased risk of developing certain types of illnesses in the biologic therapy group or not.

We are different from a clinical trial, as we do not influence the treatment you receive, but rather watch what happens when you take the treatment that your consultant prescribes you. Although these treatments are prescribed by the NHS there is still a need to monitor their **impact in the long term**, which is the main role of the BILAG BR.

By taking part in the study you are helping us build up the amount of data we have for analysis. With more data, we will be able to reach **better-informed conclusions** on the long-term safety of the treatments.

Protecting your data

All of the data we receive is treated confidentially, and your identifiable information will strictly not be shared with anyone outside the study team, aside from **NHS Digital** for data-flagging purposes. NHS Digital (or NHSCR in Scotland) collect data on health outcomes across the UK in collaboration with the NHS. Examples of this data include information on any UK resident who dies or develops a cancer. When a study participant is flagged, in the rare event that one of these health outcomes occurs, the researchers are informed. This means we have lifelong follow-up for all participants, providing maximum information about long-term use of biologic therapy in people with lupus.

Thank you for your ongoing valuable contribution to this research.

What is biologic therapy?

- Biologic therapy is a special kind of treatment, defined because of the way it is made. Biologic drugs use substances that are made from living organisms, and use the body's natural immune system to treat a disease. This can be done by stimulating or suppressing part of the immune system to help the body fight the disease. Biologic therapies used to treat lupus include rituximab and belimumab.

What are biosimilars?

- Biologic therapies have been used to treat lupus in the UK for around 10 years and many of these drugs have now reached the end of their patents which means that other manufacturers can make similar versions of these medicines, known as biosimilars. This will result in a greater choice of treatments for patients available in the NHS but because these drugs are not exactly identical to the original biologics, the BILAG BR study has been extended to follow patients receiving these new drugs.

If you want to read more about biologics and biosimilars, there is information available on the NHS website: www.nhs.uk/conditions/biological-and-biosimilar-medicines/

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Quality of Life questionnaires

We've mentioned that our aim is to follow the progress of biologic patients and a comparison group of patients receiving non-biologic therapies.

As well as gathering data from consultants, we also want to hear directly from patients about how their quality of life is affected by lupus, and track whether this changes over time, which is why we send you patient questionnaires to fill in.

We realise that these can be time consuming and not always pleasant to complete, so we really appreciate any that you're able to send back to us. This applies whatever treatment you're getting, including if you have stopped taking a drug that you were taking when you joined the study.

We value all the information you give us, so it's great if you're able to answer the whole questionnaire, however we do understand if there are questions you don't wish to answer. If you come to a question you'd rather not answer, please just leave it blank and move on to the next one.

Part of our role here involves collecting data for patients who are receiving the biologic drug belimumab (trade name Benlysta). You may know that this is a relatively new drug which has been approved to treat lupus in a particular group of patients. We've been asked to try and gather as much quality of life data as we can for belimumab patients, which, together with clinical data, will enable researchers to carry out further analysis into the use of this drug for people with lupus.

Patient diaries

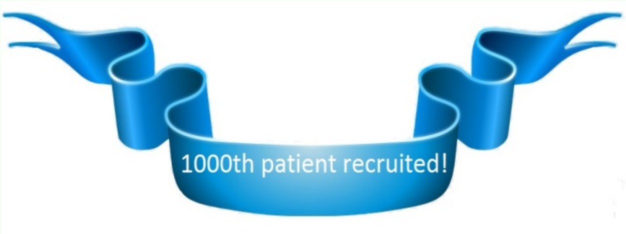
As part of the BILAG BR study we collect data on what's known as 'adverse events' – this term covers any illnesses, injuries or other life events that participants experience such as pregnancy.

The data we collect from your consultant includes information about any illnesses and injuries that you have experienced since the last follow up. However, we know that consultants don't always have the full picture. For example, they may not be aware if a participant has had emergency treatment at a different hospital.

This is why we're always grateful when participants complete the patient diaries that we send out with our quality of life questionnaires. We're particularly interested in hospital stays, pregnancies, and infections that meant you needed to have intravenous antibiotics.

We realise that when you're feeling unwell, filling in a form may be the last thing you want to do, but if you're able to give us details once you've recovered that is really helpful. This information is vitally important for us in terms of monitoring the safety of biologic drugs compared to standard treatment, so we really appreciate your help.

We're delighted to announce that we recently recruited our 1000th participant!



This is a real milestone for us and means that we're gathering a really significant amount of data to feed into lupus research.

Of course this wouldn't be possible without participants who are willing to take part in BILAG BR, so thanks again for your support – it really makes a difference!

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RESEARCH UPDATE

Read about some of the work that our researchers have been doing with the data that you've provided – thanks again for taking part.

Sophie Collinson: a researcher working with the BILAG BR

Sophie is an academic foundation year 2 doctor who qualified from medicine at the University of Manchester in 2017. She has always had a strong interest in musculoskeletal and kidney diseases since starting her undergraduate studies. In 2015 she completed a Master of Research degree, which used a novel form of 3D microscopy to investigate genetic kidney disease in children.

Sophie has continued to develop her love of research by working with the Centre for Musculoskeletal Research at The University of Manchester, under the supervision of Dr Ben Parker (Consultant Rheumatologist).

Over the past 4 months Sophie has used BILAG BR data to describe the demographics and disease activity of lupus nephritis patients in the UK, and to provide early evidence of the beneficial effects of Rituximab therapy on lupus kidney disease. She has also focused on the eligibility of lupus nephritis patients for clinical trial entry to see if these trials accurately represent those affected by the disease.

Sophie hopes to become an anaesthetist and intensive care physician with specialist interest in renal medicine. In her spare time she enjoys Crossfit training, spending time with family and looking after animals.

How can we predict which lupus drug will work for each patient?

Around half of lupus patients respond well to each lupus drug, but at the moment doctors don't know whether an individual patient will do well or badly. BILAG BR is carrying out research to find out what features of a patient mean they will do well on drugs commonly used to treat lupus. We are looking at patients' data and blood and urine samples. We have also just started collecting leftover kidney tissue from earlier biopsies, and we are very grateful to the patients who have given additional consent for us to do this.

We are excited that we are beginning to find differences between patients that, with further testing, could tell us whether a patient is likely to do better on specific drugs. To date, we have found chemicals in the blood and promising results in the kidney biopsies. When we know what factors predict response to individual drugs, it could be possible to develop an 'algorithm' (formula) that would tell a doctor which drug is most likely to succeed for each patient.

More research and publications

Already, researchers have used data from BILAG BR to look at:

- the short term effectiveness and safety of rituximab for patients whose lupus doesn't respond well to other treatments. The conclusions were:
    - rituximab is safe and is associated with improvement in disease activity in these patients, and with a reduction in steroid use
    - early vigilance for infection post-infusion is important to further improve treatment risks and benefits

  Read more here: https://academic.oup.com/rheumatology/article/57/3/470/4688912
- the percentage of lupus patients who could potentially be eligible for treatment with belimumab. It was found that between 2010 and 2015, 13% of patients who started biologic therapy for lupus in the UK would have been eligible. Read more here: https://academic.oup.com/rheumatology/article/56/6/1041/3739778

As the study continues, more data will become available for analysis, making the BILAG BR register even more useful for lupus researchers. Look out for further updates in the future!

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Dietary Advice for Patients on Biologic Therapy

One of the areas that researchers here at the Biologic Studies Group have looked at is infections in patients who are receiving biologic therapy. Our researchers found that, although the risk of bacterial infections (such as listeria and salmonella) was low in patients on biologic therapy, our data suggests it could be lowered further by following the advice issued by the Food Standards Agency (FSA) for all patients on treatments which affect the immune system.

To further reduce the risk of these types of infections, the FSA advise that certain types of food should be avoided such as:

Blue veined cheese

Unpasteurised milk and ice-cream

Pâté

Undercooked eggs

Feta and goats cheese

Finding more information about lupus and available support

- **Lupus UK** is an organisation whose aim is to provide information and support for people with lupus. **You can contact them on 01708 731251 or look at their website for more information**: www.lupusuk.org.uk Lupus UK has an very active and well-established online community which they administer and moderate – you can find it here: **www.healthunlocked.com/lupusuk**
- The **Lupus Trust** is an online resource and community for lupus patients, carers, medical professionals and fundraisers. **www. Lupus.org.uk**
- **The Lupus Site** is an online guide for lupus patients and their families: **www.thelupussite.com**
- **Versus Arthritis** (formerly Arthritis UK and Arthritis Care) is a charity which campaigns on behalf of people with arthritis and lupus and funds research into making a difference to the lives of people with lupus: **www.versusarthritis.org**
- Also, here at the **BILAG BR** we have recently launched our new website, which has information about the study for participants as well as healthcare professionals: **https://sites.manchester.ac.uk/bilag/**

The **BILAG BR** is coordinated at the University of Manchester; the study coordinator Dr Emily Sutton has been involved since the very beginning and is helped by project administrator Alison Fountain. We are available to answer any questions you have about the study but are unfortunately unable to provide any medical advice regarding your lupus; for this, you should contact your hospital care team.

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