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

Autumn 2021

Welcome to the BILAG BR study newsletter. We hope you are all well and safe after this very difficult 18 months, and would like to thank you for taking part in BILAG BR. In this newsletter we aim to provide information and updates about the study – please contact us with any comments or suggestions.

The study has continued to run throughout the Covid-19 pandemic, with a few changes:

- We've continued to collect your clinical data via your hospital care team, and though there may be some gaps due to postponed clinic visits, or visits being done remotely, the data we've received is still very valuable. As hospitals return to non-Covid research we expect to be able to collect more complete data.
- We've been unable to send out patient questionnaires, but we plan to restart soon. We'll include a diary for you to record any hospital visits or new medication – it's very useful for us to have this information, especially if we haven't been able to collect it from your hospital care team in the last year.

Lupus and Covid-19

We're aware that many people with lupus have concerns about Covid-19, Covid-19 vaccination and the potential effect of lupus treatments on their immune system. For medical advice, it's always best to speak to your hospital care team. The charity LUPUS UK also has some general guidance on their website which you may find useful: https://www.lupusuk.org.uk/covid19-vaccination/

We've set up an additional BILAG BR Covid-19 survey and blood tests you can take part in – you'll find an information sheet, consent form and paper survey with this newsletter. We'll use the results from these to help rheumatology doctors advise people with lupus on medications, Covid-19 vaccinations and infection risk. If you decide to take part you can choose which parts of this extra research you agree to – please let us know on the consent form/online consent page. We're working with Dr Mia Rodziewicz to carry out this research:

> *'Hi everyone, I am a rheumatology doctor currently taking time out of my clinical training to undertake research in lupus. I am particularly interested in how we might predict early on who is unlikely to respond to standard treatments for lupus. The COVID-19 pandemic has been an uncertain and challenging time especially for many people with lupus. I want to ensure the advice that we give you about the risk of COVID-19 infection is accurate and based on evidence. The opportunity to take part in this study will help us to generate important evidence on which to base your care. Thank you for reading!'*


Dr Mia Rodziewicz

Latest research findings using BILAG BR data

- **We previously reported on BILAG BR data and samples being used to try to predict which treatments would work for each patient**. This project has now finished and the researchers have produced formulae (algorithms) that aim to predict response better than in current standard of care. Following future research to validate the results, the ultimate goal is that care for SLE patients can be improved by putting them on the right drug, sooner. Read more here: https://sites.manchester.ac.uk/masterplans/
- **Researchers have used BILAG BR data to investigate how patients with lupus starting a new treatment compare to those with lupus who enter clinical drug trials.** (These trials determine the effectiveness and safety of new medications using tightly controlled conditions.) The researchers found that only 37% of patients entering the BILAG BR would be eligible for recruitment to clinical drug trials based on criteria set out by drug companies for recruitment to these trials. Reasons for ineligibility include severe kidney involvement, use of restricted medications (such as high doses of steroid) or other coexisting illnesses such as previous cancer or chronic kidney disease. Lupus patients with higher number of co-existing illnesses such as heart and kidney disease were less likely to be eligible to participate. This highlights the importance of collecting data from the BILAG BR to show the effectiveness and safety of biological therapies in a real world setting, particularly for patients with other health conditions.
- **Researchers have also used BILAG BR data to look at the effectiveness of rituximab in the treatment of neuro-psychiatric lupus**, where it was found to be associated with improvement.

You can read more on our website: https://sites.manchester.ac.uk/bilag/

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 **nearly 1500** 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.

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Biologic Studies Group

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/

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.

CONTACT US:

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