BIR

Biologic Interventions Register

BADBIR Patient Newsletter 2016

Get to know BADBIR in 30 seconds

- **B**ritish **A**ssociation of **D**ermatologists **B**iologic **I**nterventions **R**egister (BADBIR)
- We are a drug safety register interested in studying the long term safety of drug treatments for psoriasis.
- Our aim is to recruit over 20,000 participants by 2028 (current study end date).

Want to know more about the work we do and how we do it?

Visit www.badbir.org

Getting to know YOU in 30 seconds

1. Your doctor or someone in his/her team will discuss BADBIR with you if you meet the following criteria for the study:

- Have a diagnosis of psoriasis
- Provide written informed consent
- Currently under the care of a dermatologist

2. Via your dermatologist BADBIR will follow your progress with treatment on a regular basis.

If you are interested in participating but have not been approached, please talk to your dermatologist today.

BADBIR Sites

Thanks to all BADBIR participants we currently hold **12,265** patients on the BADBIR registry *(as of 02/06/2016)* and have **153** centres recruiting for BADBIR across the UK and Eire

Just a small note to say a BIG thank you to all BADBIR participants. We could not do it without you!

Are you wondering what your contribution will mean for research? Then visit page 2 where we explain BADBIR in more detail...

We welcome staff and patients to follow BADBIR on twitter @BADBIR

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Background

BADBIR is an observational research study that was set up by the British Association of Dermatologists (BAD) in 2007 and has been running successfully since.

The biologic drugs have been carefully tested in clinical trials before being approved for use. However, as clinical trials are run for a relatively **short** period of time, have **limited numbers** of participants compared with those which will be ultimately treated with the drug and may **exclude** patients with additional diseases (co-morbidities), it may mean that the picture might not be complete in terms of long-term use.

In contrast, BADBIR will collect data on patients treated with biologics attending regular dermatology clinics over a long period (current study end date 2028). Patients who have co-morbidities will also be included therefore the results are more likely to be more representative of the "real world" use of these drugs.

NHS
National Institute for Health and Clinical Excellence

NICE has recommended that all patients in the UK and Eire treated with biologic agents for psoriasis are registered with BADBIR. Please visit the following website for more information on NICE http://www.nhs.uk/NHSEngland/thenhs/healthregulators/Pages/nice.aspx

What is our main aim?

BADBIR aims to assess the long-term safety of a group of psoriasis treatments called biologics. A biologic is a protein based drug taken from living cells handled in a laboratory. Biologics target specific parts of the immune system that play a role in developing psoriasis.

How we plan to achieve our aims

The study is designed such that a large group of patients being treated with the newer therapies (biologics) are compared to an equally large group of patients treated with older therapies (conventional).

Currently, patients starting or switching the following drugs are asked to take part:

Biologics	**Conventional**
Humira (adalimumab)	acitretin
Enbrel (etanercept)	ciclosporin
Stelara (ustekinumab)	fumaric acid esters
Cosentyx (secukinumab)	hydroxycarbamide
Benepali (etanercept biosimilar)	methotrexate
	oral PUVA

In the past, BADBIR also recruited patients receiving Raptiva (efalizumab) and Remicade (infliximab).

Most of the dermatology units in the UK and Republic of Ireland (see map) are taking part in this research programme and subject to patient consent, the dermatology team provide data to BADBIR.

Rates of untoward medical events will be compared between the groups and the results will then be used to provide patients with a better picture of any increased risk of the new therapies.

What YOUR contribution means

By participating, you will help 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 biologic treatments.

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What has BADBIR found?

Since 2007 (study start date) BADBIR has published many articles in medical journals that detail findings from BADBIR research. Here are summaries of two articles published in 2015:

Paper 1: Baseline characteristics of patients with psoriasis enrolled in the BADBIR register

Aim of this research

The characteristics of patients with psoriasis starting biologic therapies are well described in clinical trials. We aimed to describe the characteristics, severity of psoriasis and additional medical conditions or comorbidities of patients with psoriasis upon enrolment onto BADBIR, and to highlight differences in those starting biologics compared with those on conventional systemic therapies.

What we found

As of August 2014, 8399 patients with moderate-to-severe psoriasis were registered with BADBIR.

Patient and disease characteristics

Patients enrolled in BADBIR:

- Were on average 46 years old
- Had an average disease duration of 21 years.
- Individuals in the biologic group had a higher average age and longer duration of psoriasis
- 64% biologic patients had severe or moderate-to-severe psoriasis
- 63% conventional patients had severe or moderate-to-severe psoriasis
- The majority of the patients were male (58%) of white ethnicity (90%).
- 47% of the patients enrolled reported a family history of psoriasis in a first degree relative.

Treatment for psoriasis at enrolment

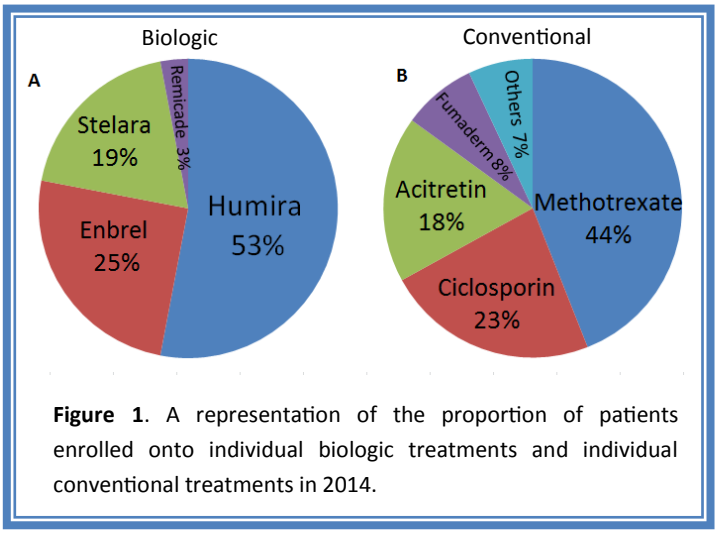

Figure 1. A representation of the proportion of patients enrolled onto individual biologic treatments and individual conventional treatments in 2014.

Patients' comorbidities (additional diseases) at enrolment

- **Obesity**: Nearly 40% of the patients were obese at enrolment with a higher proportion of obese patients in the biologic group (45%) with mean body mass index (BMI) score 31. In the conventional group 38% of the patients were classed as obese with mean BMI 30.
- **High blood pressure** (26% patients)
- **Depression** (22% patients)
- **Psoriatic Arthritis** (17% patients)
- **Multiple comorbidities:** In total 71% of all patients had comorbidities and 47% had more than one comorbidity. 54% of patients in the biologic group reported multiple comorbidities and 38% of patients on conventional systemic therapies reported multiple comorbidities.

What does this information mean for patients with psoriasis?

The data described here confirm that psoriasis is a complex disease associated with several comorbidities that may have a significant impact on patients' quality of life and on their response to treatment.

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Paper 2: Drug survival of biologic therapies for the treatment of psoriasis

What question did this research aim to answer?

We know a lot about biologic therapies for treatment of psoriasis from clinical trials. However, the way that these drugs are used in outpatient clinics is different from how they are used in clinical trials. In particular, clinical trials exclude patients with other long-term conditions. To understand how these drugs are used in real-world situations, we need to look at "drug survival". "Drug survival", defined by the length of time a patient stays on a drug, measures a number of characteristics of the treatment, for example how effective a drug continues to be through time; or whether a drug is likely to be stopped because of a side effect; or how well patients tolerate the treatment etc.

What did we do?

We investigated the drug survival of the four commonly used biologic therapies for the treatment of psoriasis – Humira, Enbrel, Remicade and Stelara – for patients who have never been treated with a biologic therapy before.

Table 1. The number of patients receiving each biologic drug that were used for the drug survival investigation.

Biologic drug	Humira	Enbrel	Remicade	Stelara
Number of patients on drug	1879	1098	96	450

What did we find?

The survival rate, a measure of the proportion of patients remaining on a drug after a certain period of time, was 77% after one year overall dropping to 53% after 3 years.

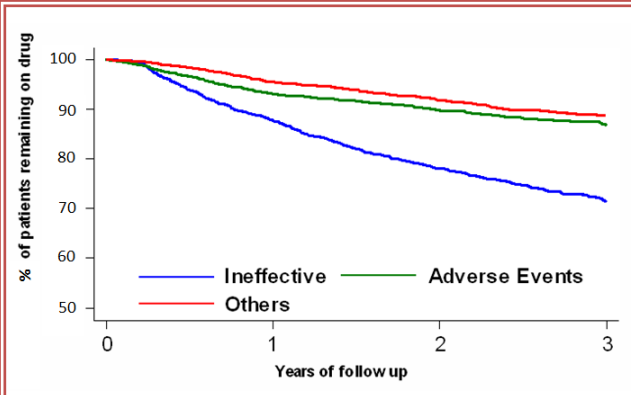
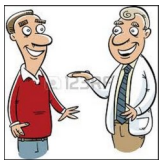


Figure 1. A graph to show the proportion of patients remaining on a biologic drug after the first 3 years of BADBIR follow-up and the reasons for stopping treatment (indicated by the coloured lines). Inefficacy is when the drug loses its power to treat the disease. An adverse event is any unfortunate medical event which affects the patient's health whilst he/she is on the BADBIR register.

- Compared with patients on Humira, patients on Stelara were 52% less likely to stop therapy, while patients on Remicade and Enbrel were 56% and 63% (respectively) more likely to stop therapy over the study period.
- Current smokers and female patients were more likely to discontinue their biologic therapy over the study period.
- Impaired quality of life at baseline was linked to an increase in the likelihood of stopping therapy.
- Patients who also have psoriatic arthritis, on the other hand, are less likely to stop their therapy over the study period.

What does this information mean for patients with psoriasis?



This information will form the basis of an informed discussion around biologic therapies i.e. the likelihood that, over time, patients will stop their treatment for a variety of reasons. It will assist patients and their doctors to choose the right biologic therapy for them at the start. It also highlights the fact that smoking is associated with a higher probability of discontinuation of a biologic therapy, and may facilitate discussions around smoking cessation prior to the planned start of a biologic therapy.