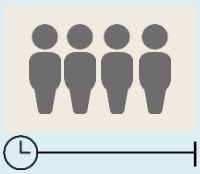
BADBIR Patient Newsletter 2019

British
Association of
Dermatologists
Biologics and
Immunomodulators
Register **(BADBIR)**

BADBIR is a drug safety register seeking to assess the long-term safety of drug treatments for psoriasis. The British Association of Dermatologists has recommended that all patients in the UK receiving newer therapies for psoriasis should be registered with BADBIR. Once a patient has agreed to participate in BADBIR, information is collected via the dermatology team and entered onto the BADBIR database.

Purpose of BADBIR



Drugs have been carefully tested for safety in clinical trials. However these trials are:

- run for a relatively short period of time
- have limited numbers of participants
- may exclude patients with additional diseases (co-morbidities)

BADBIR was established to assess the **long term safety** of newer drugs by following a real world population of psoriasis patients i.e. people of different ages, races and medical histories from all areas of the U.K. and Republic of Ireland.

A big Thank You to all participants!
We begin 2019 with **161** participating centres across the United Kingdom and Republic of Ireland and over **17,427** registrations

What's New?

We invite researchers and patients to follow @BADBIR

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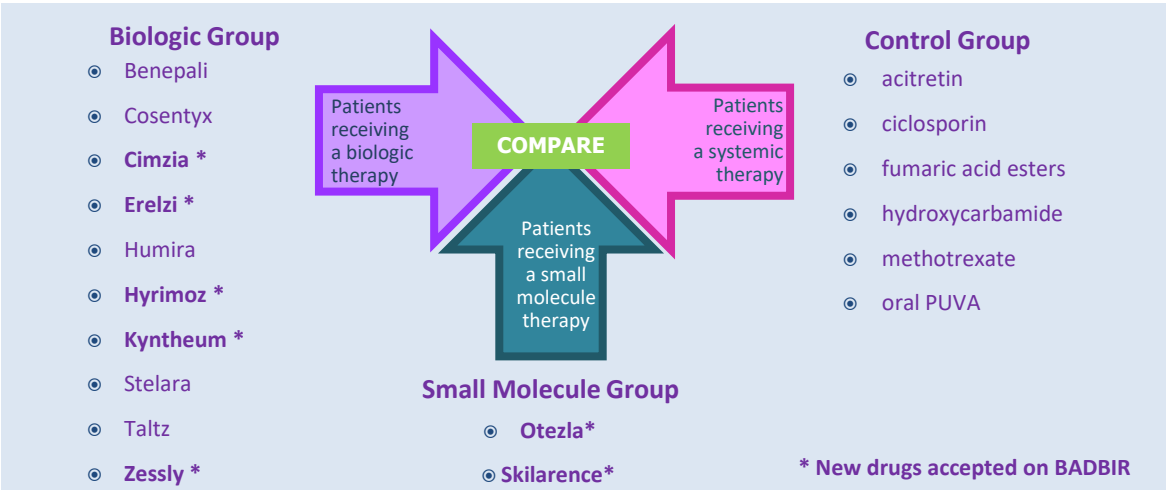
STUDY DESIGN UPDATES

New Drug Group

BADBIR is now monitoring an additional group of drugs named the small molecule group. The study will compare the rates of safety events within each group.



New Questionnaire

Recent research shows that 22% of psoriasis patients registered on BADBIR suffer from depression hence it has been suggested that routine screening questionnaires such as the Hospital Anxiety and Depression Scale (HADS) should be used in clinic to improve detection so that appropriate treatment can be offered. For this reason, approval was sought to include the HADS to other patient reported assessments in BADBIR.

Study Consent

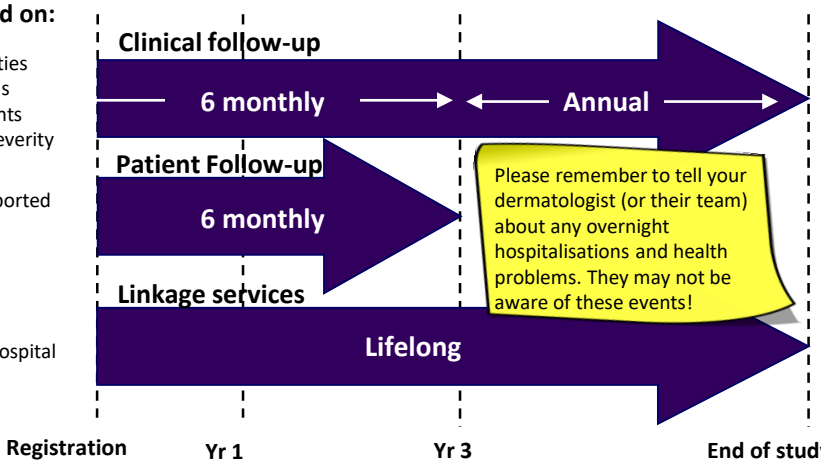
Your identifiable information will not be shared with anyone, aside from the linkage services referenced in the latest version (V5) of the information sheet and consent form. We share information with national providers of healthcare data so that the BADBIR study can receive information about your health that may not have been collected via your clinical follow-up. These organisations provide data services covering any **hospital admissions** you have had, **cancer details** if you have been diagnosed with cancer and in the event of patient death we receive the **causes of death**. For participants who consented using a version prior to 5, an application was made to the national Confidentiality Advisory Group to approve this data linkage. Further details can be found on our website at www.badbir.org/participants

This figure illustrates the type of data collected during your BADBIR participation; from registration to the end of the study.

For further details on linkage visit http://www.badbir.org/Participants/Linkage/

Data collected on:

- Comorbidities
- Drug details
- Safety events
- Psoriasis severity
- Patient Reported Measures
- Lifestyle
- Cancers
- Deaths
- Inpatient hospital admissions



Research Update

2017/8 Research Paper Summaries

1. Risk of Serious Infection in Patients with Psoriasis Receiving Biologics

Purpose Serious infection is a concern for patients with psoriasis receiving biologic therapies as these treatments can compromise the immune system. This study was carried out to find out if biologic patients have an increased risk of serious infection compared to psoriasis patients receiving non-biologic therapies.

Results

- Patients receiving Humira, Enbrel and Stelara did not have a significantly higher risk of serious infections as compared to patients receiving conventional systemic drugs.
- There was no difference in the risk of serious infections between Humira, Enbrel and Stelara.

CONCLUSION
The risk of serious infection should not be a primary concern for patients and clinicians when deciding between these treatment options.

2. Drug Survival of Second-Line Biologic Therapies in Patients with Psoriasis

Purpose Drug survival, defined by the length of time a patient stays on a drug, is an indicator of how effective a drug continues to be over time and /or whether a drug is stopped because of a side effect etc. If the first biologic used to treat the patient (first-line therapy) is not effective or the patient experiences side effects their dermatologist may start them on a different biologic. This is known as a second-line biologic therapy. This study was carried to find out how successful second-line biologics are for patients.

Results

- 77% of patients who were switched to a second biologic continued on the new treatment for at least 12 months. This dropped to 58% of patients continuing treatment in year 3.
- Stelara had the highest drug survival rate over 3 years of treatment.
- Second-line discontinuation due to adverse events (AEs) was more common among those who discontinued first-line treatment due to AEs.

CONCLUSION
Patients experiencing treatment failure with one biologic therapy can benefit from switching to another biologic.

3. Intentional and Unintentional Medication Non-Adherence in Psoriasis

Purpose Medication non-adherence can be intentional, where patients make a deliberate decision not to follow the prescribed medication schedule, or unintentional such as forgetting to take the medication. It is important to understand why patients do not adhere to drugs in order to identify the risk factors of non-adherence. This study was carried out to find out if such risk factors can be targeted in order to improve treatment effectiveness .

Results

- 22.4% of patients using self-administered systemic therapies are classified as non-adherent.
- Patients using an oral conventional systemic agent were more likely to be non-adherent compared to those using Enbrel or Humira.
- The risk factors associated with non-adherence were strong medication beliefs i.e. the patient having strong medication concerns and poor habit strength; a weaker routine of taking their medication.

CONCLUSION
Medication beliefs and habit strength can be targeted to develop strategies that can improve adherence in psoriasis.

References

1. Yiu et al. *Risk of Serious Infection in Patients with Psoriasis Receiving Biologic Therapies: A Prospective Cohort Study from the British Association of Dermatologists Biologic Interventions Register (BADBIR).* JID 2018; 138(3): 534–541
2. Iskandar et al. *Differential Drug Survival of Second-Line Biologic Therapies in Patients with Psoriasis: Observational Cohort Study from the British Association of Dermatologists Biologic Interventions Register (BADBIR).* JID 2018; 138(4): 775-784
3. Thorneloe et al. *Intentional and Unintentional Medication Non-Adherence in Psoriasis: The Role of Patients' Medication Beliefs and Habit Strength.* JID 2018; 138(4): 785–794

Research Update

2017/8 Research Paper Summaries

4. Generating EQ-5D-3L Utility Scores from the DLQI

Purpose The Dermatology Life Quality Index (DLQI) is the most widely used questionnaire to assess quality of life related to skin disease in psoriasis studies. However it is not relevant to other diseases and therefore when comparisons are required the information collected is not transferable. The EQ-5D-3L questionnaire is used to assess quality of life across all diseases and in healthy individuals. The National Institute for Health and Care Excellence (NICE) includes EQ-5D-3L as part of the standardised assessment when making a decision on whether a drug should be made available to patients on the NHS. This study was carried out to determine if information collected using the DLQI can be used by researchers to predict a EQ-5D-3L score.

Results

- The results of this study demonstrated that it was possible to reasonably predict EQ-5D-3L utility scores from the DLQI data. A user-friendly freely accessible tool has been produced to enable analysts to use this system.

CONCLUSION

Although it remains preferable to use scores derived directly from the EQ-5D-3L, this system can be used to generate utility estimates in future evaluations of treatment for patients with psoriasis.

5. Comparison of Drug Discontinuation, Effectiveness and Safety Between Clinical Trial Eligible and Ineligible Patients in BADBIR

Purpose Patients with psoriasis enrolled in clinical trials of biologics may not be similar to those treated in dermatology clinic. This could mean that results achieved in clinical trials e.g. safety and efficacy may be different when drugs are used in the "real world". There is evidence that patients who would not meet the entry criteria for such trials (ineligible) have a greater risk of serious adverse events (SAEs), but the effect on drug discontinuation and effectiveness are unknown.

Results

- Psoriasis patients receiving biologic therapy who were identified as ineligible for clinical trials were twice as likely to experience a serious adverse event (SAE) when compared with eligible patients in the first 12 months of treatment.
- These same ineligible patients had significantly lower levels of improvement in their psoriasis when compared with eligible patients in the first 12 months of treatment (Humira, Enbrel and Stelara).
- There were no differences in overall discontinuation rates between eligible and ineligible categories for any of the biologics investigated.

CONCLUSION

Psoriasis patients enrolled in clinical trials on biologics are not entirely representative of real-world patients. Dermatologists should be mindful of these differences when counselling patients on biologic treatment.

6. Cumulative Exposure to Biologics and Risk of Cancer in Psoriasis Patients: Psonet studies from Israel, Italy, Spain, United Kingdom and Republic of Ireland

Purpose In theory, there may be an increased risk of cancer following long-term exposure to biologic therapies in patients with psoriasis. The aim of this study was to assess the relationship between total length of exposure to biologic therapy and risk of cancer.

Results

- *Psonet* comprises independent drug safety registries that collaborate to investigate the long-term safety and effectiveness of biologic and systemic therapies in patients with moderate-to-severe psoriasis.

- In this study the total length of exposure to biologics was found not to be associated with the risk of developing cancers, even after considering the effect of age, gender, location, previous exposure to methotrexate, ciclosporin and phototherapy, duration of psoriasis, and other medical conditions.

CONCLUSION

Total length of exposure to biologic therapies in psoriasis patients treated in real-world clinical practice does not appear to be linked to a higher risk of cancer after several years of use.

References

4. Davison et al. *Generating EQ-5D-3L Utility Scores from the Dermatology Life Quality Index: A Mapping Study in Patients with Psoriasis. Value in Health 2017; 21(8): 1010-1018*

5. Mason et al. *Comparison of Drug Discontinuation, Effectiveness, and Safety Between Clinical Trial Eligible and Ineligible Patients in BADBIR. JAMA 2018; 154(5): 581-588*

6. Garcia-Doval et al. *Cumulative exposure to biologics and risk of cancer in psoriasis patients: A meta-analysis of Psonet studies from Israel, Italy, Spain, United Kingdom and Republic of Ireland.* BJD 2018