



NEWSLETTER

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09TH JULY 2007

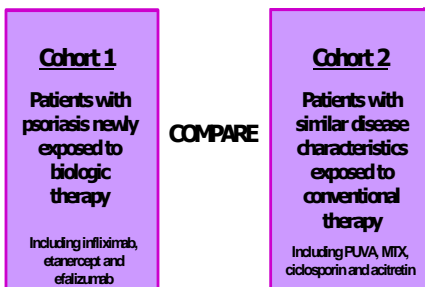
Aim of the Register

To investigate the long-term outcome of patients with psoriasis treated with biologics and compare it to those patients treated with conventional systemic treatments (ciclosporin, methotrexate, acitretin and PUVA).



Recommendation from NICE and BAD that all patients treated with biological therapy should be registered with BADBIR

Study Design



Primary Endpoints

- Any malignancy
- Any infection requiring hospitalisation
- Serious adverse events
- Death

Sample size

Accounting for losses to follow and deaths:

- Biologics n = 4000 (each one)
- Controls n = 4000
(Recruited over 5 years)

Data Collection

Consultant: Web based transfer
Patient: Paper questionnaires

Website: www.badbir.org/



BADBIR Office base:

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Biological Cohort Eligibility Criteria

- Diagnosis of psoriasis
- Newly commencing on etanercept, infliximab or efalizumab
- Informed consent
- Aged 16+ yrs

Comparison Cohort Eligibility Criteria

- Diagnosis of psoriasis
- Starting or switching conventional therapy
- Informed consent
- Aged 16+ yrs

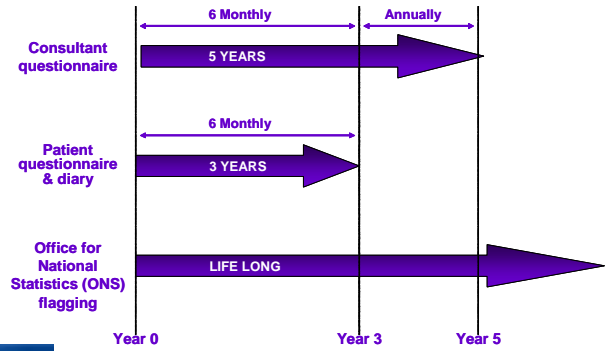
Baseline Data

Consultant

- Diagnosis and disease characteristics
- PASI
- DLQI
- EuroQoL
- Previous and current therapy

Patient

- Demographics
- Occupational Status



Follow-up data

Consultant

- Changes in therapy
- Adverse event information including pathology/microbiology reports
- Current PASI

Patient

- DLQI
- EuroQoL
- 6 monthly diary to record hospitalisations, new drugs and referrals

Pilot Study

BADBIR received MREC approval in March 2007. The pilot study will commence during August/September 2007. Seven initial centres have been approached to take part in the pilot study. The aims of the pilot are to:

- Test the proposed data collection tools
- Test and streamline the online data collection process
- Assess easiest methods for obtaining LREC/R&D approval for local recruiting centres



Funding

To help towards time spent collecting this data the following payment plan is available:

- Fully completed baseline form: £100
- Fully completed follow-up form: £50
(total of 8 follow-up forms over five years)

Each centre will need to inform BADBIR which account to pay this to

