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

**Cohort 1**
Patients with psoriasis newly exposed to biologic therapy
- Diagnosis of psoriasis
- Starting or switching conventional therapy
- Informed consent
- Aged 16+ yrs

**Cohort 2**
Patients with similar disease characteristics exposed to conventional therapy
- Diagnosis of psoriasis
- Informing consent
- Aged 16+ yrs

Comparison Cohort
Patients with psoriasis newly exposed to biologic therapy
- Diagnosis of psoriasis
- Starting or switching conventional therapy
- Informed consent
- Aged 16+ yrs

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/

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.

BADBIR Office base:
arc Epidemiology Unit
The University of Manchester
Oxford Road
Manchester
Study Coordinator: Kathy McElhone
Phone: 0161 603 7731
Email:kathleen.mcelhone@manchester.ac.uk

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