PRED4

Anti-TNF induced adverse skin reactions in IBD (ANTS)

Case Report Form

Study (bar) Code

NB: You may also enter data via the web-based portal on **www.ibdresearch.net**

On completion, please return to:
Exeter IBD and Pharmacogenetics Research Office
The Research, Innovation, Learning and Development Centre (RILD)
Barrack Road
Exeter
EX2 5DW

1.1 Inclusion criteria

- ☐ Patient currently aged ≥ 6 years
- ☐ History of ulcerative colitis (UC) or Crohn's disease (CD)
- ☐ Current or past history of anti-TNF therapy.
- ☐ No past history of eczema or psoriasis prior to starting anti-TNF therapy.
- ☐ Development of specified skin lesion whilst receiving anti-TNF therapy or within 8 weeks of drug withdrawal.
- ☐ Patient is able to provide informed consent.

1.2 Type of case

- ☐ 1. Historical case
- ☐ 2. Incident case (rash present at the time of study visit)

1.3 Patient eligibility

Is the participant eligible to take part in the research project based on the above criteria?

- ☐ Yes
- ☐ No

If no, please give reason(s) for screen failure:

Investigator's name (print) _____ Date dd / mm / yyyy

2.1 Patient details

Date of Birth dd / mm / yyyy Sex: M ☐ F ☐

2.2 Ethnicity - *Please tick as appropriate*

White

- ☐ British
- ☐ Irish
- ☐ Any other White background

Black or Black British

- ☐ Caribbean
- ☐ African
- ☐ Any other Black background

Mixed

- ☐ White and Black Caribbean
- ☐ White and Black African
- ☐ White and Asian
- ☐ Any other Mixed background

Chinese or Other Ethnic Group

- ☐ Chinese
- ☐ Any other ethnic group (*please specify*)
- ☐ Not stated

Asian or Asian background

- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ Any other Asian background

2.3 Participant informed consent

Main study

Date participant signed written consent form dd / mm / yyyy

Consent to submit anonymised clinical photographs dd / mm / yyyy

Date of blood sample taken (2 EDTA's, 1 serum sample) dd / mm / yyyy

Please ensure that if the participant consents to the optional Part 2 skin biopsies, that 2 serum samples are taken and the 2nd sample processed as per ANTS SOP.

Name of person taking consent (print)

Designation

Hospital name

3.1 **History of previous skin disease?** ☐ Yes ☐ No

3.2 If yes, which one?

3.3 History of:
- i) Asthma ☐ Yes ☐ No
- ii) Hay fever ☐ Yes ☐ No

3.4 Family history of:
- i) Skin disease ☐ Yes ☐ No
  - If yes, please specify
- ii) Atopy ☐ Yes ☐ No
- iii) Anti-TNF skin lesions ☐ Yes ☐ No

3.5 Other significant medical history ☐ Yes ☐ No

If yes, please give details here

3.6 Smoking history

☐ Never smoked

☐ Ex smoker

☐ Current smoker

3.6.1 Start date dd / mm / yyyy

3.6.2 End date dd / mm / yyyy

3.6.3 Maximum number of cigarettes per day

** Please consult with the study participant to complete section 3*

4.1 Inflammatory Bowel Disease

☐	Crohn's disease	Date of diagnosis	dd / mm / yyyy
☐	Ulcerative colitis	Date of diagnosis	dd / mm / yyyy
☐	IBD unclassified	Date of diagnosis	dd / mm / yyyy

5.1 Which anti-TNF agent was suspected of causing the skin reaction?

☐ Infliximab ☐ Adalimumab ☐ Golimumab

5.1.1 Date anti-TNF first commenced dd / mm / yyyy

5.1.2 Dose and frequency of anti-TNF

5.1.3 Was this the patient's first anti-TNF? ☐ Yes ☐ No

5.1.4 Previous anti-TNF drugs used?

☐ Infliximab ☐ Adalimumab ☐ Golimumab

5.2 Presentation

5.2.1 Date of onset of adverse skin reaction dd / mm / yyyy

5.2.2 Clinical Findings

☐ Redness
☐ Scale
☐ Alopecia

5.2.3 Location of Skin rash

☐ Scalp/hair
☐ Face
☐ Arms ☐ Flexural ☐ Extensor
☐ Legs ☐ Flexural ☐ Extensor
☐ Trunk
☐ Nails
☐ Palms/soles
☐ Genitalia including flexural sites

5.2.4 Which diagnosis/category best describes the adverse skin reaction
(please tick at least one major and if possible one minor subheading)

☐ **Psoriasis** ☐ chronic plaque ☐ psoriasiform eczema ☐ other specify ☐

☐ **Eczema** ☐ atopic ☐ seborrhoeic ☐ varicose ☐ discoid ☐ pompholyx
☐ unclassified

☐ **Palmoplantar pustulosis**

☐ **Skin infection** ☐ fungal ☐ bacterial ☐ viral
☐ recurrent pustular lesions in context of inflammatory skin rash

☐ **Lupus** ☐ discoid lupus erythematosus ☐ subacute cutaneous lupus
☐ malar rash

☐ **Drug reaction**

☐ **Other** (please specify) ☐

Approximate duration of symptoms ☐ days

5.3 Blood test results

Test (nearest result to development of skin lesion)	**Date**	**Results**
CRP	dd / mm / yyyy	
ANA	dd / mm / yyyy	
Anti-DsDNA	dd / mm / yyyy	
ENA	dd / mm / yyyy	
Anti-TNF drug level Infliximab Adalimumab Golimumab	 dd / mm / yyyy dd / mm / yyyy dd / mm / yyyy	
Antibody level	dd / mm / yyyy	

5.4 Action(s) taken

	Date	Treatment details	Response to intervention
Dermatology opinion	dd / mm / yyyy		N/A
Skin biopsy (if yes, please provide copy of result)	dd / mm / yyyy		N/A
Drug withdrawn	dd / mm / yyyy		
Topical treatment (emollients, corticosteroids, other)	dd / mm / yyyy		
Ultra-violet light therapy	dd / mm / yyyy		
Systemic treatment - steroids	dd / mm / yyyy		
Other (please specify)	dd / mm / yyyy		

5.5 Did patient require hospital admission at any stage due to the skin reaction?

☐ Yes ☐ No ☐ Unknown

If yes, date of admission dd / mm / yyyy

Date of discharge dd / mm / yyyy

Details

5.6 Anonymised photograph(s) of affected area

Scanned or digital image of past or current affected area ☐ Yes ☐ No

Please state body site of image

5.7 Optional skin biopsies (please see PRED4 protocol)

If skin lesions present at time of study visit please approach patient for optional skin biopsies.

Patient approached ☐ Yes ☐ No

Skin Biopsy consent form completed ☐ Yes ☐ N/A

Date participant signed written consent form dd / mm / yyyy

Date of skin biopsies (x4) dd / mm / yyyy

Date of additional serum sample *(please process as per ANTS SOP)* dd / mm / yyyy

Name of person taking consent (print)

Designation

Hospital name

Site 1 biopsies from affected area: 2 biopsies from skin reaction site.

Location of site 1

Photo of site 1 before biopsy ☐ Yes ☐ No

Skin biopsy site 1 - proceed as follows:
Place one biopsy in RNA later Tissue Protect tube and one in specimen pot containing formalin following instructions for shipment.

Site 2 biopsy: 2 biopsies from unaffected area.

Location of site 2

Photo of site 2 before biopsy ☐ Yes ☐ No

Skin biopsy site 2 - proceed as follows:
Place one biopsy in RNA later Tissue Protect tube and one in specimen pot containing formalin following instructions for shipment.

Study voucher given to patient ☐ Yes ☐ No

5.8 Other comments

If you have any other comments regarding this patient please give them here.

Please record below the concomitant medications taken in the 3 months prior to the adverse skin reaction.

Drug name	Dose and frequency	Start date	Stop date
		dd / mm / yyyy	dd / mm / yyyy
		dd / mm / yyyy	dd / mm / yyyy
		dd / mm / yyyy	dd / mm / yyyy
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		dd / mm / yyyy	dd / mm / yyyy

I have reviewed this CRF and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant. All entries were made either by myself or by a person under my supervision who has signed the delegation log.

Principal Investigator's signature

Date dd / mm / yyyy

Principal Investigator's name (print)

ONCE SIGNED, NO FURTHER CHANGES CAN BE MADE TO THIS CRF WITHOUT A SIGNED DATA QUERY FORM