International IBD Genetics Consortium

PRED4

Anti-TNFα Induced Demyelination

Case Report Form

Please stick study label here

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

Anti-TNFα Induced Demyelination
Introduction

Please complete all boxes where indicated and in black ball point pen.

If you make a mistake please put a line through the box, initial and date and write answer to the side.

Complete dates in format dd/mm/yyyy

The patient identification number is the bar code on the front of the CRF. Please transcribe this on to the top of the page in each relevant section.

For study inclusion participants must meet all the major criteria and any number of the additional minor criteria.

*Other potential causes of neurological symptoms

Acute disseminated encephalomyelitis (ADEM), Behcet's disease, polyarteritis nodosa, Sjögren's disease, anti-phospholipid syndrome, systemic lupus erythematosus (SLE), sarcoid, Infections (such as HIV, Lyme, neurosyphilis, Listeria, Progressive multifocal leukoencephalopathy [PML]), Vitamin B12 deficiency

This study covers both central nervous system (CNS) and peripheral nervous system (PNS) demyelination.

Anti-TNFα Induced Demyelination

Section 1 - Inclusion Criteria

Study code ☐

1.1 Major criteria (all must be met)

☐ History of exposure to anti-TNFα antibody at any time in the past

☐ No history of demyelinating neurological symptoms prior to exposure to Anti-TNFα antibody

☐ Neurological symptoms lasting at least 24 hours

☐ MRI brain and/or spinal cord shows changes consistent with CNS demyelination; or electrophysiological tests (nerve conduction or evoked potentials) are consistent with PNS or CNS demyelination.

☐ CNS or PNS inflammatory demyelination confirmed by Neurologist

☐ Neurological opinion implicates anti-TNFα medication as possible cause of demyelination, and if the patient is still receiving the drug, it is withdrawn

1.2 Other potential causes for neurological symptoms (see page 2)*

☐ No - Category A

☐ Yes - Category B

If yes, please specify ☐

1.3 Minor criteria:

☐ Resolution (partial or complete) of symptoms on drug withdrawal (with or without specific treatment)

☐ Recurrence of symptoms on re-challenge with anti-TNFα antibody

1.4 Number of minor criteria ☐

1.5 Participant's eligibility Investigator sign-off

Is the participant eligible to take part in the clinical trial? ☐ Yes ☐ No

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

1.
2.
3.

Investigator's signature ☐ Date dd / mm / yyyy

Investigator's name (print) ☐

Section 2 - Patient Details

Study code

2.1 Patient details

Date of Birth dd / mm / yyyy

Sex: M F

Weight at time of initial anti-TNFα dose (or nearest weight) kg

Height cm

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

Date participant signed written consent form dd / mm / yyyy

Date of blood sample taken dd / mm / yyyy

Section 3 - Medical History

Study code

3.1 Hospital Details

3.1.1 Consultant Gastroenterologist/ Rheumatologist/Dermatologist

Hospital

Hospital address

Consultant telephone

Consultant email

3.1.2 Consultant Neurologist

Hospital

Hospital address

Consultant telephone

Consultant email

3.2 Medical History

3.2.1 Indication for Anti-TNFα medication:

- ☐ Inflammatory bowel disease – Crohn's Disease/Ulcerative Colitis
- ☐ Rheumatoid Arthritis
- ☐ Ankylosing Spondylitis
- ☐ Seronegative spondyloarthropathies
- ☐ Psoriasis
- ☐ Other, please specify:

3.3 Comorbidities ☐ Yes ☐ No

3.3.1 Hypertension ☐ Yes ☐ No Date of diagnosis dd / mm / yyyy

3.3.2 Diabetes ☐ Yes ☐ No Date of diagnosis dd / mm / yyyy

- ☐ Type I — Using insulin: ☐ Yes ☐ No
- ☐ Type II — Date commenced insulin dd / mm / yyyy

Section 3 - Medical History

Study code

3.3.3 Severe peripheral vascular disease ☐ Yes ☐ No

Date of diagnosis dd / mm / yyyy

3.3.4 Myocardial infarction ☐ Yes ☐ No

Date of diagnosis dd / mm / yyyy

3.3.5 TIA/CVA ☐ Yes ☐ No

Date of diagnosis dd / mm / yyyy

3.4 Other significant medical history ☐ Yes ☐ No

If yes, please give details here

3.5 Smoking History

3.5.1 ☐ Never Smoked ☐ Ex Smoker ☐ Current Smoker

3.5.2 Start Date dd / mm / yyyy

3.5.3 End Date dd / mm / yyyy

3.5.4 Maximum number of cigarettes per day

Section 4 - Anti-TNFα History

Study code

4.1 Anti-TNFα Medication

	Date Anti-TNFα Medication commenced	Date Anti-TNFα Medication ceased	Dose of Anti-TNFα Medication	Number of doses
Infliximab	dd / mm / yyyy	dd / mm / yyyy		
Adalimumab	dd / mm / yyyy	dd / mm / yyyy		
Certolizumab pegol	dd / mm / yyyy	dd / mm / yyyy		
Etanercept	dd / mm / yyyy	dd / mm / yyyy		
Other, please specify	dd / mm / yyyy	dd / mm / yyyy		

4.2 Date of onset of neurological symptoms

dd / mm / yyyy

4.3 Please describe the patient's symptoms

4.4 Please describe the neurological examination findings

4.5 Had the patient ever had an MRI brain and/or spinal cord BEFORE the onset of this episode

☐ Yes ☐ No ☐ Unknown

If yes what was the date of this scan dd / mm / yyyy

Was a contrast agent used? ☐ Yes ☐ No ☐ Unknown

If yes, please specify

Please copy report text below or attach photocopy of report after anonymisation

4.6 Did the patient have an MRI Brain and/or spinal cord AFTER the onset of neurological symptoms?

☐ Yes ☐ No ☐ Unknown

If yes what was the date of this scan dd / mm / yyyy

Was a contrast agent used? ☐ Yes ☐ No ☐ Unknown

If yes, please specify

Please copy report text below or attach photocopy of report after anonymisation

Section 4 - Anti-TNFα History

Study code

4.7 Did the patient have a lumbar puncture/CSF examination?

☐ Yes ☐ No ☐ Unknown

If yes, please give findings or attach photocopy of report after anonymisation

4.8 Did the patient have evoked potentials (EP) carried out - Visual (VEP), Somatosensory (SSEP) or Brainstem Auditory (BAEP)?

☐ Yes ☐ No ☐ Unknown

Please copy report text below or attach photocopy of report after anonymisation

4.9 Did the patient have nerve conducting studies?

☐ Yes ☐ No ☐ Unknown

Please copy report text below or attach photocopy of report after anonymisation

4.10 Did the patient have any other investigations?

☐ Yes ☐ No ☐ Unknown

If yes, please give details

4.11 Did the patient require hospital admission?

☐ Yes ☐ No ☐ Unknown

If yes: Date of admission dd / mm / yyyy

Date of discharge dd / mm / yyyy

4.12 Did the patient require any specific treatment?

☐ Yes ☐ No ☐ Unknown

If yes, what treatment was given?

☐ Intravenous Immunoglobulin (IVIG)

☐ Steroids

☐ Plasma exchange

☐ Other, please specify

4.13 Disease course (please tick one of the following)

☐ Episode of demyelination with **complete** resolution of symptoms

How long did it take for symptoms to resolve (days)?

☐ Episode of demyelination with **partial** or **no** resolution of symptoms

☐ Relapse-remitting episodes, characterised by further acute symptoms of demyelination

☐ Progressive symptoms

4.14 Was the patient rechallenged with the same or another anti-TNFα agent?

☐ Yes ☐ No ☐ Unknown

If yes: Which anti-TNFα was used?

Date started dd / mm / yyyy Dose and frequency

Did symptoms recur? ☐ Yes ☐ No ☐ Unknown

If Yes Date of recurrence dd / mm / yyyy

Details

Date of Drug withdrawal dd / mm / yyyy

4.15 Family history of multiple sclerosis or peripheral nerve disorder?

☐ Yes ☐ No ☐ Unknown

If yes, please give details

Section 4 - Anti-TNFα History

Study code

4.16 Family history of anti-TNFα induced demyelination?

☐ Yes ☐ No ☐ Unknown

If yes, please give details

Section 5 - Other Drug History

(in the last 3 months prior to development of neurological symptoms)

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

Anti-TNFα Induced Demyelination

Section 6 - Principal Investigator Statement Study code

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