

International IBD Genetics Consortium

PRED4

Anti-TNF α Induced Demyelination

Case Report Form

Please stick study label here

On completion, please return to:

Tracey Hill / Claire Bewshea
Inflammatory Bowel Disease Research Office
Room 422 Noy Scott House
Royal Devon & Exeter Hospital (Wonford)
Barrack Road, Exeter, EX2 5DW, UK

Anti-TNF α 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-TNF α Induced Demyelination

Section 1 - Inclusion Criteria

Study code

1.1 Major criteria (all must be met)

- History of exposure to anti-TNF α antibody at any time in the past
- No history of demyelinating neurological symptoms prior to exposure to Anti-TNF α antibody
- Neurological symptom 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anti-TNF α medication as possible cause of demyelination, and if the patient is still receiving the drug, it is withdrawn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 (sum number of criteria):

- Resolution (partial or complete) of symptoms on drug withdrawal (with or without specific treatment)
- Recurrence of symptoms on re-challenge with anti-TNF α 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)

Anti-TNF α Induced Demyelination

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-TNF α 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

Anti-TNF α Induced Demyelination

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-TNF α 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

Anti-TNF α Induced Demyelination

Section 4 - Anti-TNF α History

Study code

4.1 Anti-TNF α Medication

	Date Anti-TNF α Medication commenced	Date Anti-TNF α Medication ceased	Dose of Anti-TNF α 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

Anti-TNF α Induced Demyelination

Section 4 - Anti-TNF α History

Study code

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

Anti-TNF α Induced Demyelination

Section 4 - Anti-TNF α 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

Anti-TNF α Induced Demyelination

Section 4 - Anti-TNF α History

Study code

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-TNF α agent?

- Yes No Unknown

If yes: Which anti-TNF α was used?

Did symptoms recur?

Yes

No

Unknown

4.15 Family history of multiple sclerosis or peripheral nerve disorder?

- Yes No Unknown

If yes, please give details

4.16 Family history of anti-TNF α induced demyelination?

- Yes No Unknown

If yes, please give details

Anti-TNF α 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 and Signature Log.

Principal Investigator's signature

Date

Principal Investigator's name (print)

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