International IBD Genetics Consortium

5-Aminosalicylate Induced Nephrotoxicity

Case Report Form

Study Code

Please stick study label here

On completion, please return to:
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Inflammatory Bowel Disease Research Office
Room 422 Noy Scott House
Royal Devon & Exeter Hospital (Wonford)
Barrack Road, Exeter, EX2 5DW, UK

5-Aminosalicylate Induced Nephrotoxicity
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.

In the absence of a diagnostic test for 5-ASA induced nephrotoxicity, definitions are below.

For study inclusion participants must meet all the major criteria and any number of the additional 4 minor criteria. The presence or absence of other risk factors for renal disease distinguishes category B from category A patients. Patients will be classified A0-4 or B0-4 depending upon the number of minor criteria met. Thus a diagnosis of 5-ASA induced nephrotoxicity will be most confident in patients designated A4 and least confident in those designated B0.

*Other risk factors

Drugs

Penicillins, Cephalosporins, Ciprofloxacin, Sulphonamides, Rifampicin, Furosemide, Bumetanide, Thiazides, Allopurinol, Cimetidine, Omeprazole, Lansoprazole, Indinavir

Comorbidities

Uncontrolled hypertension, Diabetes, severe peripheral vascular disease

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Section 1 - Inclusion Criteria

Study code ☐

1.1 Major criteria (all must be met)

☐ Patient aged 16 or over

☐ Normal creatinine or eGFR at baseline

☐ ≥ 50% rise in serum creatinine (with corresponding fall in eGFR), any time after introduction of 5-ASA

☐ Medical opinion implicating 5-ASA justifies drug withdrawal, even if temporary

1.2 Other risk factor(s) for renal disease (see page 2)*

☐ No - Category A

☐ Yes - Category B

1.3 Minor criteria (sum number of criteria):

☐ Rise in serum creatinine within 12 months of introduction of 5-ASA

☐ Renal biopsy demonstrates interstitial nephritis

☐ Fall in serum creatinine ≥ 20% from peak (with corresponding rise in eGFR), on withdrawal of 5-ASA *with or without* use of steroids

☐ Recurrence with re-challenge, ≥ 20% rise in serum creatinine (with corresponding fall in eGFR), any time after introduction

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

Initials | Date of Birth dd / mm / yyyy | Sex: M F

Weight when diagnosed with IBD (or nearest estimate) 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

- 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

3.11 Consultant Gastroenterologist

Hospital

Hospital address

Consultant telephone

Consultant email

3.12 Consultant Nephrologist

Hospital

Hospital address

Consultant telephone

Consultant email

3.2 Comorbidities Yes ☐ No ☐

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

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

☐ Type I

☐ Type II

Using insulin: Yes ☐ No ☐

Date commenced insulin dd / mm / yyyy

3.23 Severe peripheral vascular disease Yes ☐ No ☐

Date of diagnosis dd / mm / yyyy

3.24 Other significant medical history Yes ☐ No ☐

If yes, please give details here

Section 4 - Diagnosis & Classification of IBD

Study code

4.1 Diagnosis and classification of IBD

☐ 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

4.2 Family history

Family history of IBD (1st and 2nd degree relatives) Yes ☐ No ☐ Unknown ☐

If yes, give details

Family history of 5-ASA induced nephrotoxicity Yes ☐ No ☐ Unknown ☐

If yes, give details

4.3 Ulcerative colitis

4.31 According to the Montreal classification, the extent of ulcerative colitis can be classified as:

- ☐ E1 Ulcerative proctitis - inflammation is limited to the rectum (proximal extent of inflammation is distal to the rectosigmoid junction)
- ☐ E2 Left sided UC (distal UC) - inflammation limited to a proportion of the colorectum up to the splenic flexure
- ☐ E3 Extensive UC (pancolitis) - inflammation extends beyond the splenic flexure
- ☐ Ex Unknown

4.32 Disease severity in 2 years prior to development of renal impairment

- ☐ S0 Clinical remission. Asymptomatic; no escalation of treatment
- ☐ S1 Mild relapses – managed with oral or rectal aminosalicylates and/or rectal steroids: **no oral steroids** required
- ☐ S2 Moderate relapses requiring oral steroids and/or addition of immunomodulator
- ☐ S3 Severe or refractory disease requiring inpatient admission or colectomy

4.4 Crohn's disease

4.41 Location

- ☐ L1 Ileal
- ☐ L2 Colonic
- ☐ L3 Ileocolonic
- ☐ L4 Isolated upper disease

4.42 Behaviour - the behaviour can be defined by looking at reports from Barium enema, colonoscopy, MRI, CT

- ☐ B1 Non stricturing, non-penetrating
- ☐ B2 Stricturing
- ☐ B3 Internal penetrating
- ☐ p Perianal disease modifier

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Section 5 - Renal History

Study code

5.1 Presentation

Did the patient present because of:

- ☐ Routine monitoring
- ☐ Opportunistic blood test
- ☐ Clinical manifestation of renal failure

5.2 Pre-existing renal disease

Any known pre-existing renal disease Yes ☐ No ☐ Unknown ☐

5.3 Baseline renal function

	Creatinine (µmol/l)	Normal range as per lab report	eGFR (ml/min)	Date	Urinalysis	Date
Renal function pre IBD diagnosis						
Renal function at diagnosis of IBD						
Latest Renal function prior to starting 5-ASA						

5.4 Abnormal renal function

	Creatinine (µmol/l)	Normal range as per lab report	eGFR (ml/min)	Date	Urinalysis	Date
Renal function first abnormal						
Abnormal renal function first recognised						
Worst renal function						
Worst Creatinine clearance						

5.5 Recovered renal function

	Creatinine (µmol/l)	Normal range as per lab report	eGFR (ml/min)	Date	Urinalysis	Date
Best recovered renal function						

Time to best recovered renal function (days)

Section 5 - Renal History

Study code

5.6 Peak blood eosinophil count

(within 3 months of abnormal renal function being recognised)

Date dd / mm / yyyy Count (x10^9/L)

5.7 Renal biopsy

Yes ☐ No ☐ If yes, date of renal biopsy dd / mm / yyyy

Histology of renal biopsy

Was the patient re-challenged with a 5-ASA? Yes ☐ No ☐

What happened to renal function on re-challenge?

5.8 Treatment of 5-ASA nephrotoxicity

Were steroids used? Yes ☐ No ☐

Date steroids started? Date dd / mm / yyyy Dose

Date steroids stopped? Date dd / mm / yyyy

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Section 6 - ASA Drug History from Diagnosis Study code

Drug	Route (oral/PR)	Dose	Start date mm / yyyy	Stop date mm / yyyy	Non-renal side effects

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Section 7 - Other Drug History

Study code

(in 12 months prior to development of renal impairment)

Drug	Route (oral/PR)	Dose	Start date mm / yyyy	Stop date mm / yyyy	Non-renal side effects

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Section 8 - 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.

Prinicpal 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