

# International IBD Genetics Consortium

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## 5-Aminosalicylate Induced Nephrotoxicity

### Case Report Form

#### Study Code

Please stick study label here

**On completion, please return to:**

Tracey Hill

Study Coordinator

Inflammatory Bowel Disease Research Office

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# 5-Aminosalicylate Induced Nephrotoxicity

## Definitions

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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.

### Major criteria (all must be met)

- Normal creatinine or eGFR at baseline
- $\geq 50\%$  rise in serum creatinine (with corresponding fall in eGFR), any time after introduction of 5-ASA
- Expert renal opinion implicates 5-ASA

### Other risk factor(s) for renal disease\*

- No - Category A
- Yes - Category B

### 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  $\geq 20\%$  from peak (with corresponding rise in eGFR), on withdrawal of 5-ASA *with or without* use of steroids
- Recurrence with re-challenge,  $\geq 20\%$  rise in serum creatinine (with corresponding fall in eGFR), any time after introduction

Category A/B

Number of minor criteria

### \*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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Completed by

Date form completed

dd / mm / yyyy

## Patient Details

Initials

Date of Birth

dd / mm / yyyy

Sex

Hospital no

## 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

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## Hospital Details

Consultant Gastroenterologist

Consultant Nephrologist

Hospital

Hospital

Hospital address

Hospital address

Consultant telephone

Consultant telephone

Consultant email

Consultant email

## Comorbidities

Hypertension

\_\_\_\_\_

Date of diagnosis

dd / mm / yyyy

Diabetes

\_\_\_\_\_

Date of diagnosis

dd / mm / yyyy

Type I

Using insulin:

Yes

No

Type II

Date commenced insulin

dd / mm / yyyy

Severe peripheral vascular disease

\_\_\_\_\_

Date of diagnosis

dd / mm / yyyy

Other, please specify

\_\_\_\_\_

Details

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## Diagnosis and Classification of IBD

Crohn's disease \_\_\_\_\_ Date of diagnosis

Ulcerative Colitis \_\_\_\_\_ Date of diagnosis

IBD unclassified \_\_\_\_\_ Date of diagnosis

Family history of IBD \_\_\_\_\_ Details

Family history of 5-ASA induced nephrotoxicity

Details

## Ulcerative colitis

### Maximum ever extent prior to development of renal impairment

- E1 Ulcerative proctitis
- E2 Left sided UC (distal UC) Inflammation distal to the splenic flexure only
- E3 Extensive UC (pancolitis) Inflammation extends proximal to the splenic flexure
- Ex Unknown

### 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

## Crohn's disease

### Location

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

### Behaviour

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

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## 5-ASA drug history from diagnosis

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

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## Other drug history (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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## Renal History

Weight when 5-ASA started (kg)

Height (cm)

Any known pre-existing renal disease

	Creatinine ( $\mu\text{mol/l}$ )	eGFR (ml/min)	Date	Urinalysis	Date
Renal function pre IBD diagnosis					
Renal function at diagnosis					
Latest Renal function prior to starting 5-ASA					
Renal function first abnormal					
Abnormal renal function first recognised					
Worst renal function					
Worst Creatinine clearance					
Best recovered renal function					

Time to normal renal function (days)

Time to 20% fall in peak Creatinine (days)

Time to best recovered renal function (days)

**Peak blood eosinophil count**  
(within 3 months of abnormal renal function being recognised)

Date

Count ( $\times 10^9/\text{L}$ )

dd / mm / yyyy

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 -rechallenge?

Did the patient present because of:

Routine monitoring

Opportunistic blood test

Clinical manifestation of renal failure

## 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