

International IBD Genetics Consortium

PRED4

Proton Pump Inhibitor Induced Nephritis

Case Report Form

Please stick study label here

On completion, please return to:
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Ground Floor, Child Health Building
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Proton Pump Inhibitor Induced Nephritis

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 proton pump inhibitor (PPI) 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 PPI 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, Indinavir, 5- ASA

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)

- $\geq 30\%$ rise in serum creatinine *or* $\geq 25\%$ fall in eGFR) any time after introduction of PPI
- No other risk factors for renal disease (see page 2)*
- Medical opinion implicating PPI justifies drug withdrawal, even if temporary

1.2 Minor criteria (sum number of criteria):

- Normal creatinine at baseline
- Rise in serum creatinine or fall in eGFR occurs within 12 months of introduction of PPI
- Renal biopsy demonstrates interstitial nephritis
- 25% improvement in peak creatinine or lowest eGFR on withdrawal of PPI, with or without use of steroids
- Re-challenge with any PPI leads to $\geq 30\%$ rise in serum creatinine or $\geq 25\%$ fall in eGFR any time after introduction

1.3 Number of minor criteria

1.4 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)

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Section 2 - Patient Details

Study code

2.1 Patient details

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 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

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Section 3 - Medical History

Study code

3.1 Hospital Details

3.1.1 Consultant Gastroenterologist

Hospital

Hospital address

Consultant telephone

Consultant email

3.1.2 Consultant Nephrologist

Hospital

Hospital address

Consultant telephone

Consultant email

3.2 Comorbidities

Yes No

3.2.1 Hypertension

Yes No

Date of diagnosis

dd / mm / yyyy

3.2.2 Diabetes

Yes No

Date of diagnosis

dd / mm / yyyy

Type I

Using insulin:

Yes

No

Type II

Date commenced insulin

dd / mm / yyyy

3.2.3 Severe peripheral vascular disease

Yes

No

Date of diagnosis

dd / mm / yyyy

3.2.4 Other significant medical history

Yes

No

If yes, please give details here

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Section 4 - PPI History

Study code

4.1

Brand of PPI taken	Date started	Date stopped	Maximum dose
Omeprazole	dd / mm / yyyy	dd / mm / yyyy	
Pantoprazole	dd / mm / yyyy	dd / mm / yyyy	
Lansoprazole	dd / mm / yyyy	dd / mm / yyyy	
Esomeprazole	dd / mm / yyyy	dd / mm / yyyy	
Rabeprazole	dd / mm / yyyy	dd / mm / yyyy	
Other (please specify):	dd / mm / yyyy	dd / mm / yyyy	

4.2 Family history

Family history of PPI induced nephritis:

Yes

No

Unknown

If yes, give details

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Section 5 - Renal History

Study code

5.1 Presentation

Did the patient present because of:

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

5.3.1 Latest renal function (creatinine and eGFR) prior to starting PPI (with the normal reference range please)

5.3.2 Date of latest renal function prior to starting PPI

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)

5.6 Peak blood eosinophil count

(within 3 months of abnormal renal function being recognised)

Date

Count (x10⁹/L)

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Section 5 - Renal History

Study code

5.7 Renal biopsy

Yes

No

If yes, date of renal biopsy

dd / mm / yyyy

Histology of renal biopsy

5.8 Was the patient re-challenged with a PPI?

Yes

No

If yes, which PPI was used?

What happened to the renal function on re-challenge?

5.9 Treatment of interstitial nephritis

Were steroids used?

Yes

No

Date steroids started?

dd / mm / yyyy

Dose

Date steroids stopped?

dd / mm / yyyy

5.10 Other treatment for renal failure

Did the patient require dialysis?

Yes

No

Unknown

If yes, date dialysis commenced

dd / mm / yyyy

Date dialysis ceased

dd / mm / yyyy

Was this haemodialysis or peritoneal dialysis?

Was dialysis temporary or permanent?

Did the patient require renal transplantation?

Yes

No

If yes, date of transplantation

dd / mm / yyyy

Other comments

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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.

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