

# International IBD Genetics Consortium

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**PRED4**

**Proton Pump Inhibitor Induced Nephritis**

**Case Report Forms**

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

# Proton Pump Inhibitor Induced Nephritis

## Introduction

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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 5 minor criteria. A diagnosis of PPI induced nephrotoxicity will be most confident in patients with all 5 minor criteria and least confident in those with no additional minor criteria.

### **\*Other risk factors**

#### **Drugs**

Penicillins, Cephalosporins, Ciprofloxacin, Sulphonamides, Rifampicin, Frusemide, Bumetanide, Thiazides, Allopurinol, Cimetidine, Indinavir, 5- ASA

#### **Comorbidities**

Uncontrolled hypertension, Diabetes, severe peripheral vascular disease

# Proton Pump Inhibitor Induced Nephritis

## 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)\* at the time of the renal injury
- Medical opinion implicating PPI justifies drug withdrawal, even if temporary

### 1.2 Minor 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)

# Proton Pump Inhibitor Induced Nephritis

## Section 2 - Patient Details

Study code

### 2.1 Patient details

Date of Birth

dd / mm / yyyy

Sex: M

F

Weight when diagnosed with renal failure (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

# Proton Pump Inhibitor Induced Nephritis

## 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


# Proton Pump Inhibitor Induced Nephritis

## Section 3 - Medical History

Study code

### 3.3 Smoking History

3.3.1  Never Smoked

Ex Smoker

Current Smoker

3.3.2 Start Date

3.3.3 End Date

3.3.4 Maximum number of cigarettes per day

## Section 4 - PPI History

### 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

# Proton Pump Inhibitor Induced Nephritis

## 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 ( $\mu\text{mol/l}$ )	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 ( $\mu\text{mol/l}$ )	Normal range as per lab report	eGFR (ml/min)	Date	Urinalysis	Date
Best recovered renal function						

Time to best recovered renal function (days)

# Proton Pump Inhibitor Induced Nephritis

## Section 5 - Renal History

Study code

### 5.6 Action taken

Drug withdrawn Date

Dose decreased Date

Reduced dose

Tolerated (normal renal function on this dose)  Not tolerated  Not known

### 5.7 Peak blood eosinophil count

(within 3 months of abnormal renal function being recognised)

Date

Count (x10<sup>9</sup>/L)

### 5.8 Renal biopsy

Yes  No

If yes, date of renal biopsy

Histology of renal biopsy

### 5.9 Was the patient re-challenged with a PPI?

Yes  No

If yes, which PPI was used?  Date started

Outcome:

Tolerated Dose tolerated

Not tolerated

Lowest Creatinine/eGFR (with date of test)

Date of drug withdrawal



# Proton Pump Inhibitor Induced Nephritis

## Section 5 - Renal History

Study code

### 5.10 Treatment of interstitial nephritis

Were steroids used?

Yes

No

Date steroids started?

dd / mm / yyyy

Dose

Date steroids stopped?

dd / mm / yyyy

Were any other immunosuppressants used?

Yes

No

Name of immunosuppressant used and dose

Date started?

dd / mm / yyyy

Dose

Date stopped?

dd / mm / yyyy

### 5.11 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

### 5.12 Comments



# Proton Pump Inhibitor Induced Nephritis

Section 7 - 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**