

Predicting Serious Drug Side Effects in Gastroenterology
 - PRED4
 UKIBDGC and International IBDGC project.



Welcome to this edition of the PRED 4 newsletter. Thank you all for all your support with this study. Since the last newsletter we have recruited 125 patients, new recruiting sites include Stepping Hill, Countess of Chester and Eastbourne.

**** We are on the final push for recruitment to PRED4, and we really need your help especially with the following arms;**

- ❖ **PPI induced interstitial nephritis** – we only need a further 50 cases.
- ❖ **Thiopurine induced liver injury** – we require a further 60 cases
- ❖ **Thiopurine induced hypersensitivity reaction** – a further 140 cases

Thiopurine induced liver injury (TIH) in IBD

- History of inflammatory bowel disease
- Normal ALT and bilirubin at baseline
- No history of chronic liver disease
- Elevation of ALT and/or bilirubin to ≥ 5 times upper limit of normal (normal range as per local laboratory)
- History of thiopurine exposure in the previous 30 days prior to abnormal blood test
- Medical opinion implicating thiopurine in development of hepatotoxicity leads to dose reduction/ drug withdrawal (even temporary)

PPI induced nephrotoxicity (in any patient)

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

Thiopurine induced Hypersensitivity Reaction

Inclusion Criteria

- Aged 6 years or over
- History of Inflammatory Bowel Disease
- History of thiopurine exposure in the previous 7 days before the onset of adverse event
- Flu like symptoms severe enough to lead to drug withdrawal even if temporary (symptoms should include one of the following: fever, muscle ache, joint pain)
- Onset of symptoms within 4 weeks of starting thiopurine
- Symptoms resolved within 14 days of drug withdrawal

Exclusion Criteria

- Patient tolerated re-challenge with the same thiopurine regardless of dose
- Drug withdrawn due to nausea and/or diarrhoea without any other symptoms
- Objective evidence of Infection

Targets: We are happy for you to recruit over your targets set in the SSI form so if you have reached your target please don't let that hold you back. Don't forget, if you recruit one patient to 2 arms this will mean a double NIHR CRN accrual.

Hanlie Olivier
Email.Hanlie.olivier@nhs.net
 Tel: 01392 406814

Marian Parkinson
Marian.parkinson@nhs.net
 01392 406851

Dr Tariq Ahmad (Chief Investigator)
 E-mail: tariq.ahmad1@nhs.net

Claire Bewshea –
 IBD Research Project Manager
 E-mail: claire.bewshea@nhs.net
 Tel: 01392 406850
 Mobile: 07828146468

Junior doctors:

Dr Graham Heap (TIP)
grahamheap@nhs.net

Dr Naomi Edney (PPI)
naomi.edney@nhs.net

 Twitter: You can follow up to date news on the PRED4 study at @PRED4research.

**PRED4 Hospital sites - number recruited is based on the samples logged in laboratory by:
30 June 2015**

Please note figures exclude any screening log failures or patients withdrawn

Royal Devon & Exeter Hospital	97	Great Ormond Street Hospital - Paediatric	6
Guy's Hospital, London	63	James Paget University Hospitals	6
Southampton General Hospital	53	Manchester Royal Infirmary	6
Royal Berkshire Hospital	47	Nottingham Children's Hospital - Paediatric	6
Ninewells Hospital, Dundee	40	Royal Adelaide Hospital, Australia	6
St James's University Hospital, Leeds	40	Royal Bournemouth General Hospital	6
Gloucester Royal Hospital	35	Royal Brisbane & Women's Hospital, Australia	6
Hull Royal Infirmary	30	Canberra Hospital, Australia	5
Royal Derby Hospital	30	Darlington Memorial & Bishop Auckland Hospital	5
Watford General Hospital	27	Freeman Hospital, Newcastle (RENAL)	5
Addenbrooke's, Cambridge	24	Kettering Hospital	5
Florence, Italy	24	St Vincent's Hospital, Melbourne, Australia	5
Royal London Barts Hospital	23	Yeovil District Hospital	5
Western General Hospital, Edinburgh	23	Alder Hey Children's Hospital - Paediatric	4
University Hospitals Bristol	22	Basingstoke & North Hampshire Hospital	4
University of Alberta, Canada	21	Flinders Medical Centre, South Australia	4
Nottingham University Hospitals	19	Glasgow Royal Infirmary	4
Poole Hospital	19	Lincoln County Hospital	4
Kent & Canterbury Hospital	18	Northern Devon Healthcare NHS Trust	4
Orebro University Hospital, Sweden	18	Raigmore Hospital, Inverness	4
University Hospital Padua, Italy	17	Regional Hospital Viborg, Denmark	4
Fremantle Hospital, Australia	16	Royal Blackburn Hospital	4
Stoke Mandeville Hospital, Bucks	16	Royal Liverpool & Broadgreen Hospital	4
York Teaching Hospital	16	Scunthorpe General Hospital	4
Derriford Hospital, Plymouth	15	St Vincent's Hospital, Sydney, Australia	4
Musgrove Park Hospital, Taunton	15	Worthing Hospital	4
New Cross Hospital, Wolverhampton	15	Aberdeen Royal Infirmary	3
Royal Cornwall Hospital	15	Basildon Hospital	3
Royal Hallamshire Hospital, Sheffield	15	Birmingham Children's Hospital	3
Royal Stoke University Hospital	15	County Hospital Hereford	3
Warrington Hospital	14	Leicester General Hospital - Paediatric	3
Salford Royal Hospital	14	Liverpool Hospital, Australia	3
Aintree University Hospital	12	Queen Elizabeth Hospital King's Lynn	3
Forth Valley Royal Hospital	12	Sandwell Hospital, Birmingham	3
Mater Clinic, Brisbane, Australia	12	South Africa, Groote Schuur	3
Shrewsbury & Telford Hospital	12	Southmead Hospital, Bristol	3
Queen Alexandra Hospital, Portsmouth	11	University Hospital North Tees	3
Royal Sussex County Hospital, Brighton	11	West Middlesex University Hospital	3
Torbay Hospital	11	Crosshouse Hospital, Ayrshire & Arran	2
Weston General Hospital	11	Dorset County Hospital	2
Yorkhill Children's Hospital, Glasgow - Paediatric	11	Epsom & St Helier University Hospitals	2
Bradford Royal Infirmary	10	Harrogate District Hospital	2
Chinese University of Hong Kong	10	Ipswich Hospital	2
Frimley Park Hospital	10	Kiel, Germany	2
King's College Hospital, London	10	Leeds General Infirmary - Paediatric	2
Norfolk & Norwich Hospital	10	Luton and Dunstable Hospital - Paediatric	2
Wythenshawe Hospital	10	Maidstone and Tunbridge Wells NHS Trust	2
Barnet & Chase Farm Hospitals	9	Mater Dei Hospital, Malta	2
Dudley Group of Hospitals	9	Milton Keynes Hospital	2
John Radcliffe Hospital, Oxford	9	Pennine Trust, Manchester	2
Mid Yorkshire Hospitals	9	Royal United Hospital, Bath	2
Princess Alexandra Hospital, Essex	9	Sheffield Children's Hospital - Paediatric	2
St George's Hospital, London	9	University Hospital Lewisham	2
St Mark's Hospital, Harrow	9	University Hospital of Ioannina, Greece	2
Airedale General Hospital	8	Wrightington, Wigan & Leigh	2
Calderdale Royal Hospital	8	Addenbrooke's, Cambridge - Paediatric	1
Chelsea and Westminster Hospital	8	Countess of Chester	1
Colchester General Hospital	8	Eastbourne District General Hospital	1
Dunedin Hospital, New Zealand	8	Grantham & District Hospital	1
James Cook University Hospital, South Tees	8	North Cumbria University Hospitals	1
Llandough Hospital, Cardiff	8	Queen Elizabeth Hospital, London	1
Queen Elizabeth Hospital, Birmingham	8	Royal Hampshire County Hospital	1
Royal Victoria Infirmary, Newcastle	8	Royal Manchester Children's Hospital - Paediatric	1
South Tyneside District Hospital	8	Shaare Zedek Medical Centre, Israel	1
Birmingham Heartlands Hospital	7	Stepping Hill Hospital, Stockport NHS Foundation T	1
Haifa, Israel	7	University Hospital of Wales	1
King's Mill Hospital, Nottinghamshire	7	Worcester Royal Infirmary	1
Mount Sinai, Canada	7		
Royal Free Hospital, London	7		
Tameside Hospital	7		
University College London Hospital	7	Total UK Recruited:	1236
Chesterfield Royal Hospital	6	Total International Recruited:	187
		Grand Total:	1423

SITE HAS RECRUITED SINCE LAST NEWSLETTER