



Predicting Serious Drug Side Effects in Gastroenterology - PRED4

International IBD Genetics Consortium Projects

www.ibdresearch.co.uk/pred4

Welcome to the 1st newsletter of 2014. We have 23 sites that have recruited patients in to the PRED4 arms since the last newsletter. ****Ruth Fazakerley (Leeds) and Linda Jones (Royal Berkshire)** have recruited the very first patients in to the new thiopurine induced liver injury arm and **Lynn O'Donohoe (Watford)** has recruited the first patient in to the new sulfasalazine induced neutropaenia arm. Thank you and well done**

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

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.

We have moved office and our new contact details are below:

**IBD Pharmacogenetics Research Office (CRF);
 Research, Innovation, Learning and Development
 (RILD) Centre;**

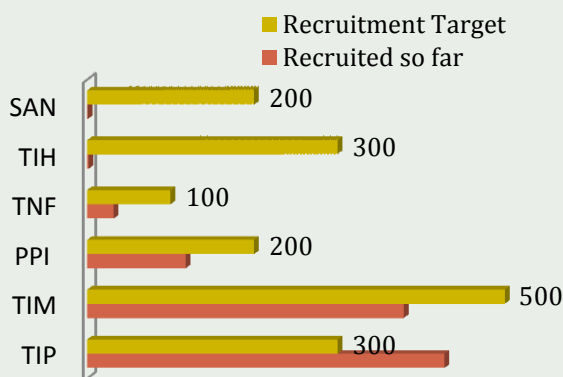
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Reminder of the inclusion criteria for the 2 new arms:

Sulfasalazine Induced Neutropaenia (SAN)

- History of inflammatory bowel disease or Rheumatoid Arthritis
- History of Sulfasalazine exposure in the previous 30 days
- Normal total white cell count and neutrophil count at baseline
- Fall in neutrophil count to $\leq 0.5 \times 10^9/L$
- Medical opinion implicating Sulfasalazine leads to dose reduction or drug withdrawal (even if temporary)

Thiopurine Induced Liver Injury (TIH)

- History of inflammatory bowel disease
- Normal ALT and bilirubin at baseline
- No pre-existing liver disease
- Elevation of ALT and/or bilirubin to ≥ 5 times upper limit of normal (guidance >175 for female and >200 for males.)
- History of thiopurine exposure in the previous 30 days prior to this abnormal blood test
- Medical opinion implicating thiopurine in development of hepatotoxicity

Hints and tips document has been updated – this has been sent out along with this newsletter.



The new CRFs are available on the database www.ibdresearch.net please contact us for your username and password.

As always if you have any feedback or suggestions on how to improve the study please let us know . If you have found a good way to find patients why not post it on Twitter.

*****Thiopurine induced pancreatitis (TIP) arm has closed*****

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**PRED4 Hospital sites - number recruited is based on the samples logged in laboratory by:
22nd January 2014**

Please note figures exclude any screening log failures or patients withdrawn

Guy's Hospital, London	54	Princess Alexandra Hospital, Essex	5
Royal Devon & Exeter Hospital	52	St Vincent's Hospital, Melbourne, Australia	5
Southampton General Hospital	37	Weston General Hospital	5
Royal Derby Hospital	26	Basingstoke & North Hants Hospital	4
Hull Royal Infirmary	25	Darlington Memorial & Bishop Auckland Hospital	4
Florence, Italy	24	Flinders Medical Centre, South Australia	4
Royal Berkshire Hospital	24	Great Ormond Street Hospital - Paediatric	4
Addenbrooke's, Cambridge	23	James Cook University Hospital, South Tees	4
St James's University Hospital, Leeds	22	King's Mill Hospital, Nottinghamshire	4
Ninewells Hospital, Dundee	21	Raigmore Hospital, Inverness	4
University of Alberta, Canada	21	Royal Blackburn Hospital	4
Western General Hospital, Edinburgh	20	Scunthorpe General Hospital	4
Orebro University Hospital, Sweden	18	South Africa, Groote Schuur	4
University Hospitals Bristol	18	St Vincent's Hospital, Sydney, Australia	4
Fremantle Hospital, Australia	16	Stoke Mandeville Hospital, Bucks	4
Nottingham University Hospitals	15	Warrington Hospital	4
Gloucester Royal Hospital	14	Aberdeen Royal Infirmary	3
Kent & Canterbury Hospital	14	Basildon Hospital	3
Royal Cornwall Hospital	14	Bradford Royal Infirmary	3
University Hospital Padua, Italy	14	Colchester General Hospital	3
Royal London Barts Hospital	13	County Hospital Hereford	3
Mater Clinic, Brisbane, Australia	12	Glasgow Royal Infirmary	3
Salford Royal Hospital	12	James Paget University Hospitals	3
Aintree University Hospital	11	Liverpool Hospital, Australia	3
Derriford Hospital, Plymouth	11	Nottingham Children's Hospital - Paediatric	3
York Teaching Hospital	11	Regional Hospital Viborg, Denmark	3
New Cross Hospital, Wolverhampton	10	Royal Free Hospital, London	3
Torbay Hospital	10	Royal Hallamshire Hospital, Sheffield	3
Watford General Hospital	10	Royal Liverpool & Broadgreen Hospital	3
John Radcliffe Hospital, Oxford	9	Sandwell Hospital, Birmingham	3
King's College Hospital, London	9	University Hospital North Tees	3
Poole Hospital	9	West Middlesex University Hospital	3
St Mark's Hospital, Harrow	9	Worthing Hospital	3
Wythenshawe Hospital	9	Alder Hey Children's Hospital - Paediatric	2
Airedale General Hospital	8	Crosshouse Hospital, Ayrshire & Arran	2
Chelsea and Westminster Hospital	8	Dorset County Hospital	2
Dunedin Hospital, New Zealand	8	Epsom & St Helier University Hospitals	2
Mid Yorkshire Hospitals	8	Harrogate District Hospital	2
Musgrove Park Hospital, Taunton	8	Kiel, Germany	2
Norfolk & Norwich Hospital	8	Leicester General Hospital - Paediatric	2
Queen Elizabeth Hospital, Birmingham	8	Luton and Dunstable Hospital	2
Royal Victoria Infirmary, Newcastle	8	Mater Dei Hospital, Malta	2
St George's Hospital, London	8	Milton Keynes Hospital	2
University Hospital North Staffordshire	8	Pennine Trust, Manchester	2
Yorkhill Children's Hospital, Glasgow - Paediatric	8	Sheffield Children's Hospital - Paediatric	2
Frimley Park Hospital	7	University Hospital of Ioannina, Greece	2
Haifa, Israel	7	Yeovil District Hospital	2
Mount Sinai, Canada	7	Ipswich Hospital	1
Queen Alexandra Hospital, Portsmouth	7	Leeds General Infirmary - Paediatric	1
Royal Sussex County Hospital, Brighton	7	Manchester Royal Infirmary	1
University College London Hospital	7	North Cumbria University Hospitals	1
Birmingham Heartlands Hospital	6	Queen Elizabeth Hospital, London	1
Calderdale Royal Hospital	6	Royal Hampshire County Hospital	1
Chesterfield Royal Hospital	6	Royal United Hospital, Bath	1
Forth Valley Royal Hospital	6	Shaare Zedek Medical Centre, Israel	1
Llandough Hospital, Cardiff	6	Southmead Hospital, Bristol	1
Royal Adelaide Hospital, Australia	6	University Hospital Lewisham	1
Royal Bournemouth General Hospital	6	University Hospital of Wales	1
Royal Brisbane & Women's Hospital, Australia	6	Worcester Royal Infirmary	1
Shrewsbury & Telford Hospital	6	Wrightington, Wigan & Leigh	1
South Tyneside District Hospital	6		
Dudley Group of Hospitals	5	Total UK Recruited:	812
Freeman Hospital, Newcastle (RENAL)	5	Total International Recruited:	169
Kettering Hospital	5	Grand Total:	981

SITE HAS RECRUITED SINCE LAST NEWSLETTER