SAE Consortium

PRED4 Newsletter December 2014

Royal Devon and Exeter NHS Foundation Trust

Predicting Serious Drug Side Effects in Gastroenterology - **PRED4**

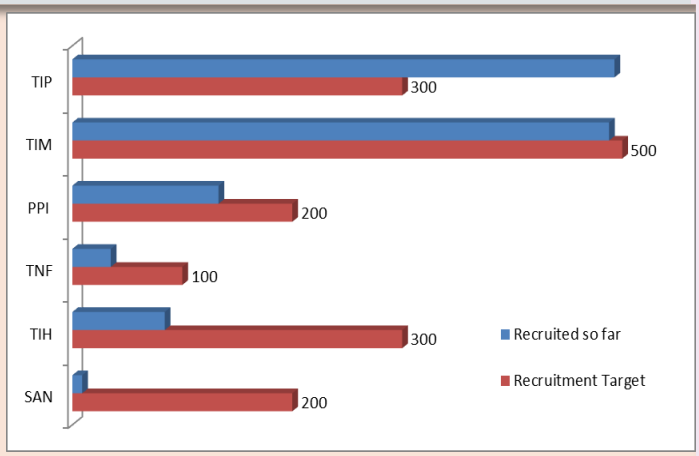
International IBD Genetics Consortium Projects

www.ibdresearch.co.uk/pred4

Welcome to the 4th edition newsletter of 2014. 38 sites have recruited patients to PRED4 since the last newsletter. We also have 4 new recruiters: Birmingham Childrens, Lincoln, Maidstone and Manchester Royal. Thank you and well done.

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

We have submitted the amendment 5 to the Research Ethics Committee and this has been uploaded on to CSP for R&D review. This amendment is to extend recruitment of all six arms of the study until December 2015 and to add a new arm to the study - Thiopurine Hypersensitivity Reaction. We have attached the CRF's for all the study arms to this newsletter. Also we would like to draw your attention to 2 patient adverts, that we hope will assist in patient identification. These have also been attached to this newsletter.



Inclusion and Exclusion criteria for the new arm: Thiopurine Hypersensitivity Reaction (THR)

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 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- Drug withdrawn due to nausea and/or diarrhoea without any other symptoms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 at the time of the hypersensitivity reaction.

Reminder of the Inclusion Criteria for 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

CHRISTMAS CLOSURE

The Pharmacogenetics Office will be closed 24th December 2014 - 5th January 2015. You can still send in samples to the lab as the lab staff will be working over this period.

If you have any urgent queries you may call our Research Nurse Suzie Marriott on 01392 408937 or 07810 834996 who will be available on 24th, 30th and 31st December and the 2nd January.

The electronic CRFs are designed to replace the paper CRFs and can be completed 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.

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We have two new programme administrators
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PRED4 Hospital sites - number recruited is based on the samples logged in laboratory by: 17th November 2014

Please note figures exclude any screening log failures or patients withdrawn

Royal Devon & Exeter Hospital	78	Royal Bournemouth General Hospital	6
Guy's Hospital, London	57	Royal Brisbane & Women's Hospital, Australia	6
Southampton General Hospital	41	Royal Free Hospital, London	6
Royal Berkshire Hospital	37	Bradford Royal Infirmary	5
St James's University Hospital, Leeds	35	Canberra Hospital, Australia	5
Ninewells Hospital, Dundee	34	Darlington Memorial & Bishop Auckland Hospital	5
Gloucester Royal Hospital	31	Freeman Hospital, Newcastle (RENAL)	5
Hull Royal Infirmary	30	James Cook University Hospital, South Tees	5
Royal Derby Hospital	26	Kettering Hospital	5
Addenbrooke's, Cambridge	24	King's Mill Hospital, Nottinghamshire	5
Florence, Italy	24	St Vincent's Hospital, Melbourne, Australia	5
University of Alberta, Canada	21	Warrington Hospital	5
Western General Hospital, Edinburgh	21	Basingstoke & North Hampshire Hospital	4
University Hospitals Bristol	20	Flinders Medical Centre, South Australia	4
Watford General Hospital	20	James Paget University Hospitals	4
Nottingham University Hospitals	18	Raigmore Hospital, Inverness	4
Orebro University Hospital, Sweden	18	Regional Hospital Viborg, Denmark	4
Poole Hospital	18	Royal Blackburn Hospital	4
Royal London Barts Hospital	18	Royal Liverpool & Broadgreen Hospital	4
Kent & Canterbury Hospital	17	Scunthorpe General Hospital	4
Fremantle Hospital, Australia	16	St Vincent's Hospital, Sydney, Australia	4
University Hospital Padua, Italy	16	Yeovil District Hospital	4
Royal Cornwall Hospital	14	Aberdeen Royal Infirmary	3
Salford Royal Hospital	14	Alder Hey Children's Hospital - Paediatric	3
Derriford Hospital, Plymouth	13	Basildon Hospital	3
Musgrove Park Hospital, Taunton	13	County Hospital Hereford	3
Aintree University Hospital	12	Glasgow Royal Infimary	3
Mater Clinic, Brisbane, Australia	12	Leicester General Hospital - Paediatric	3
New Cross Hospital, Wolverhampton	12	Liverpool Hospital, Australia	3
York Teaching Hospital	12	Sandwell Hospital, Birmingham	3
Chinese University of Hong Kong	10	South Africa, Groote Schuur	3
King's College Hospital, London	10	University Hospital North Tees	3
Royal Hallamshire Hospital, Sheffield	10	West Middlesex University Hospital	3
Torbay Hospital	10	Worthing Hospital	3
Wythenshawe Hospital	10	Crosshouse Hospital, Ayrshire & Arran	2
John Radcliffe Hospital, Oxford	9	Dorset County Hospital	2
Norfolk & Norwich Hospital	9	Epsom & St Helier University Hospitals	2
Princess Alexandra Hospital, Essex	9	Harrogate District Hospital	2
St George's Hospital, London	9	Ipswich Hospital	2
Stoke Mandeville Hospital, Bucks	9	Kiel, Germany	2
Yorkhill Children's Hospital, Glasgow - Paediatric	9	Leeds General Infirmary - Paediatric	2
Airedale General Hospital	8	Lincoln County Hospital	2
Calderdale Royal Hospital	8	Luton and Dunstable Hospital - Paediatric	2
Chelsea and Westminster Hospital	8	Mater Dei Hospital, Malta	2
Colchester General Hospital	8	Milton Keynes Hospital	2
Dunedin Hospital, New Zealand	8	Northern Devon Healthcare NHS Trust	2
Forth Valley Royal Hospital	8	Pennine Trust, Manchester	2
Frimley Park Hospital	8	Sheffield Children's Hospital - Paediatric	2
Llandough Hospital, Cardiff	8	Southmead Hospital, Bristol	2
Mid Yorkshire Hospitals	8	University Hospital Lewisham	2
Queen Elizabeth Hospital, Birmingham	8	University Hospital of Ioannina, Greece	2
Royal Sussex County Hospital, Brighton	8	Addenbrooke's, Cambridge - Paediatric	1
Royal Victoria Infirmary, Newcastle	8	Birmingham Children's Hospital	1
Shrewsbury & Telford Hospital	8	Maidstone and Tunbridge Wells NHS Trust	1
South Tyneside District Hospital	8	Manchester Royal Infirmary	1
St Mark's Hospital, Harrow	8	North Cumbria University Hospitals	1
University Hospital North Staffordshire	8	Queen Elizabeth Hospital, London	1
Birmingham Heartlands Hospital	7	Royal Hampshire County Hospital	1
Dudley Group of Hospitals	7	Royal Manchester Children's Hospital - Paediatric	1
Haifa, Israel	7	Royal United Hospital, Bath	1
Mount Sinai, Canada	7	Shaare Zedek Medical Centre, Israel	1
Queen Alexandra Hospital, Portsmouth	7	University Hospital of Wales	1
University College London Hospital	7	Worcester Royal Infirmary	1
Weston General Hospital	7	Wrightington, Wigan & Leigh	1
Chesterfield Royal Hospital	6		
Great Ormond Street Hospital - Paediatric	6	**Total UK Recruited:**	**1027**
Nottingham Children's Hospital - Paediatric	6	**Total International Recruited:**	**186**
Royal Adelaide Hospital, Australia	6	**Grand Total:**	**1213**

SITE HAS RECRUITED SINCE LAST NEWSLETTER