



STOP PRESS! Recruitment tops 200!

200 patients recruited ...
Only 102 patients to go!

- A total of 63 participants were recruited over the last 6 months (Monthly recruitment rate of 10.5 participants per month). **Thank you for all the effort!**
- Please keep trying to recruit patients ... if we keep going at our current rate of recruitment we will finish recruiting in Spring 2013.

THANKS TO EVERYONE!

Please find below recruitment figures per site (Sites given Green For Go):

Site	Green For Go	Randomised
Gartnavel General Hospital, Glasgow	02/04/2010	27
Haywood Hospital, Stoke On Trent	23/02/2011	16
Raigmore Hospital, Inverness	16/08/2010	13
Wishaw General Hospital, Wishaw	07/09/2010	12
Glasgow Royal Infirmary, Glasgow	09/06/2010	11
Barts and the London NHS Trust; London	04/11/2010	10
Poole Hospital NHS Trust, Poole, Dorset	15/06/2011	10
Western General Hospital, Edinburgh	07/07/2010	9
Torbay Hospital, Torquay	01/08/2011	8
Stobhill General Hospital, Glasgow	10/06/2010	7
James Cook University Hospital; Middlesbrough	13/05/2011	7
Royal Victoria Infirmary, Newcastle	11/03/2010	6
Royal Cornwall Hospitals NHS Trust, Truro	07/10/2011	6
Aberdeen Royal Infirmary, Aberdeen	23/09/2010	5
University of Birmingham, Birmingham	01/02/2011	5
Derriford Hospital, Derriford, Plymouth	24/08/2011	5
Basildon and Thurrock Hospitals	26/07/2011	5
Salisbury NHS Foundation Trust	26/01/2012	5
Whytemans Brae Hospital, Fife	08/11/2010	4
South London Healthcare NHS Trust, London	13/07/2011	4

Queens Hospital, Essex, Romford	31/10/2011	4
Inverclyde Royal Hospital, Greenock	05/08/2010	3
Nuffield Orthopaedic Centre, Oxford	04/04/2012	3
Borders General Hospital, Borders	08/10/2010	3
Ninewells Hospital, Dundee	04/06/2010	3
Ipswich Hospital, Ipswich	11/07/2011	3
Royal Devon and Exeter NHS Trust, Exeter	27/07/2011	2
Countess of Chester Hospital, Chester	31/01/2012	2
University of Cardiff, Cardiff	18/01/2012	1
Coventry University Hospitals, Coventry	06/01/2012	1
West Suffolk Hospital, Bury St Edmonds	21/02/2012	0
Llandudno Hospital, Llandudno	21/02/2012	0
West Herts Hospital NHS Trust, Hertfordshire	04/04/2012	0
Leicester Royal Infirmary, Leicester	10/02/2012	0
Cannock Chase Hospital, Cannock	16/08/2012	0
North Manchester General Hospital	20/08/2012	0
TOTAL		200

Star Member of Staff – Sister Janice France, Biologics Nurse, Gartnavel General, Glasgow who has helped to recruit more patients than anyone else in the UK!

Well Done and thank you!

Star Unit - Stoke on Trent have recruited 6 patients in the last three months ...

FANTASTIC ☺

Duncan's at present favorite part of the country – *has* to be the South West, where Poole, Torbay, Truro, Plymouth and Exeter have their own local rivalry to be the top SW recruiter – Poole just ahead with 10 patients with Torbay pressing hard on 8 patients ... and no fewer than **31** patients from the region.

Come on Midlands! Come on NW! ... You can't be beaten!

Only Scotland boasts more patients (95)

... but then we are a whole country ☺ ☺

... and drink Scotch ☺ ☺ ☺

Start of IMP - Timelines between visits

Please remember!

- Time your follow up visits from when treatment first starts! You should be seeing patients every calendar month thereafter
- Please consult the protocol page 8.
- Should you have any queries please contact Jurgen.

Delegation / Responsibilities logs

Many thanks for keeping us updated on the delegation and responsibilities logs. If not already done, please forward any amended delegation / responsibilities logs to Jurgen accompanied with signed CVs and GCP certificates for new study staff

Study booklets

If you require additional study booklets then please contact Jurgen or Emma who will forward to the study team Point of Contact

Patient Diaries – Cost questionnaires

We appreciate that obtaining completed patient diaries from participants (also referred to as cost questionnaires) can at times be challenging. Can we ask to make an effort to ensure that the patient diaries are returned to site and then subsequently forwarded to Emma.

Safety update

To date we have received 27 Serious Adverse Event reports involving 22 subjects. Of these 10 have been assessed as being possibly or probably related to a study drug (3 adalimumab, 6 rituximab, 1 etanercept) with one of these considered being a SUSAR.

The Pharmacovigilance Office team (Dr Eleanor Dinnett – PV officer and June Allan – PV Administrator) is happy to answer any questions you may have regarding any aspect of the SAE reporting process and can be contacted by phone at 0141 330 4744 or by email at: pharmacovig@glasgowctu.org

Cumulative List of SAEs received by the Pharmacovigilance Office to 31/07/2012:

Description	Classification	IMP
Chest Infection	SAR	Adalimumab
Chest Infection	SAR	Adalimumab
Probable Cutaneous Vasculitis	SAR	Adalimumab
Abnormal Liver Function Tests	SUSAR	Rituximab
New onset interstitial lung disease	SAR	Etanercept
Gram negative sepsis	SAR	Rituximab
Flare of RA	SAE	
Investigations for increased confusion	SAE	
Colonic Polyps	SAE	
NIDDM (Type 2 Diabetes)	SAE	
Left Groin Pain	SAE	
Septic arthritis left 2nd DIP joint	SAE	
Right Hip Replacement	SAE	
Admitted for analgesia assessment	SAE	
Laminectomy	SAE	
Chest infection	SAE	
Neutropaenia	SAR	Rituximab
Pneumonitis	SAE	
(R) total knee replacement	SAE	
Asthma	SAE	
Musculoskeletal chest pain	SAE	
Chest infection	SAR	Rituximab
Neutropenia	SAR	Rituximab
Myocardial infarction	SAE	
Non specific abdominal pain	SAR	Rituximab
Grade 2 cancer left breast	SAE	
Rheumatoid arthritis flare up	SAE	

Pharmacy update

Claire Steele who did a fantastic job of organising the Pharmacy aspects of the ORBIT Study has now left to take up a new post. A revised Pharmacy contact list will be circulated in due course. Angela Carruth and Elizabeth Douglas can still be contacted on 0141 211 8554 and queries/orders can be e-mailed to R&Dimp@ggc.scot.nhs.uk or faxed to 0141 211 2692.

Blood sampling procedures – revised blood sampling process for academic sites.

- If you require additional equipment to undertake the blood sampling process or have any queries regarding the blood sampling process, then please contact staff detailed below.
- Please remember to contact staff below on the day of forwarding samples.

Staff to be contacted are:

- Dr Becky Hands: r.e.hands@qmul.ac.uk
- Ms Rita Jones: m.r.jones@qmul.ac.uk
- Dr Vidalba Rocher: v.rocher@qmul.ac.uk
- Sudeh Riahi: s.riahi@qmul.ac.uk

QUERIES.

Should you have any queries then please contact:

- For SSI information: please contact Ann on: Ann.Tierney@ggc.scot.nhs.uk
- For Pharmacy information: please contact Elizabeth on Elizabeth.Douglas@ggc.scot.nhs.uk or R&Dimp@ggc.scot.nhs.uk
- cost questionnaires, please contact Emma on Emma.Miller@ggc.scot.nhs.uk
- For general information / queries please contact Jurgen on: Jurgen.van-melckebeke@ggc.scot.nhs.uk or Duncan on: Duncan.Porter@ggc.scot.nhs.uk

THANK YOU FOR YOUR SUPPORT IN THE STUDY!

Duncan & Jurgen.