



ORBIT STUDY NEWSLETTER
9th edition



Recruitment.

234 patients recruited ...
Only 68 patients to go!

- A total of 56 participants were recruited over the last 6 months (Monthly recruitment rate of approximately 6 participants per month). **Thank you for all the effort!**
- Can we please ask to have a last push for all sites; if all sites recruit another 2 participants then we have reached our recruitment target!

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	29
Haywood Hospital, Stoke On Trent	23/02/2011	17
Wishaw General Hospital, Wishaw	07/09/2010	16
Raigmore Hospital, Inverness	16/08/2010	13
Glasgow Royal Infirmary, Glasgow	09/06/2010	13
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
Royal Cornwall Hospitals NHS Trust, Truro	07/10/2011	9
Torbay Hospital, Torquay	01/08/2011	8
Royal Victoria Infirmary, Newcastle	11/03/2010	8
Stobhill General Hospital, Glasgow	10/06/2010	7
James Cook University Hospital; Middlesbrough	13/05/2011	7
Derriford Hospital, Derriford, Plymouth	24/08/2011	7
Basildon and Thurrock Hospitals	26/07/2011	7
Nuffield Orthopaedic Centre, Oxford	04/04/2012	7
University of Birmingham, Birmingham	01/02/2011	6
Aberdeen Royal Infirmary, Aberdeen	23/09/2010	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

Leicester Royal Infirmary, Leicester	10/02/2012	3
Inverclyde Royal Hospital, Greenock	05/08/2010	3
Borders General Hospital, Borders	08/10/2010	3
Ninewells Hospital, Dundee	04/06/2010	3
Ipswich Hospital, Ipswich	11/07/2011	3
University of Cardiff, Cardiff	18/01/2012	3
King George Hospital, Essex	02/10/2012	3
Royal Devon and Exeter NHS Trust, Exeter	27/07/2011	2
Countess of Chester Hospital, Chester	31/01/2012	2
Cannock Chase Hospital, Cannock	16/08/2012	2
Coventry University Hospitals, Coventry	06/01/2012	1
Llandudno Hospital, Llandudno	21/02/2012	1
West Suffolk Hospital, Bury St Edmonds	21/02/2012	0
West Herts Hospital NHS Trust, Hertfordshire	04/04/2012	0
North Manchester General Hospital	20/08/2012	0
New Cross Hospital, Wolverhampton	29/08/2012	0
Royal Lancaster Infirmary, Lancaster	22/11/2012	0
Kettering General Hospital	13/11/2012	0
TOTAL		234

Star Members of Staff – Nurse Consultant Catherine McClinton and Dr Catherine Swales - Nuffield Orthopaedic Centre - Oxford who have recruited the most patients in the last reporting period! **Well done and thank you!**

Star Units - Wishaw General Hospital, Lanarkshire and Nuffield Orthopaedic Centre, Oxford have both recruited 4 patients in the last three months ... **FANTASTIC ☺**

Teleconferences November 2012.

Many thanks for everyone who attended the teleconferences. The TCs proved popular and a good forum to inform all sites on latest progress inclusive of time for questions and answers. Thank you for the participation!

New Investigator Meeting 2013.

A final ORBIT Investigator Meeting is planned to take place at the British Society of Rheumatology (BSR) event which takes place 23-25 April 2013 in Birmingham. Details of the Investigator Meeting will be forwarded to you in due course. Duncan and Jurgen hope to meet you at the event.

New staff joining the team – Existing staff leaving the team

It is extremely important - in order to stay within regulations - to inform Jurgen and Emma if there is a change of local study staff. Should this happen then please let us know as soon as possible and we will be in touch to ask for updated delegation / responsibilities log, GCP certificates and CVs.

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

Completion and subsequent forwarding of the questionnaires remains challenging. The main reasons are that patients do not complete them or forget to return. Can we ask to make sure all efforts are made in order that we have completed diaries for all participants. Emma will make contact with all the sites and provide them with a list of missing diaries.

Safety update

NHS GGC PHARMACOVIGILANCE OFFICE ARRANGEMENTS -CHRISTMAS/NEW YEAR PERIOD 2012/2013

The Pharmacovigilance Office will be closed from the close of business on Friday 21st December 2012 until Thursday 3rd January 2013. The PV Office will however access emails and faxes during that time.

Please continue to fax any Serious Adverse Event (SAE) forms to the usual Pharmacovigilance fax number (+44(0)141 357 5588). If the SAE is considered by the investigator to be a Suspected Unexpected Serious Adverse Event (SUSAR) please also email the Pharmacovigilance Office (pharmacovig@glasgowctu.org) to advise us that the fax has been sent.

Any SUSARs received will be reported by the PV office to the MHRA and the appropriate Ethics Committee in line with regulatory requirements.

- To date we have received 35 Serious Adverse Event reports involving 28 subjects. Of these 13 have been assessed as being possibly or probably related to a study drug (5-adalimumab, 7-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 17/12/2012:

Description	Classification	IMP
Chest infection	SAR	Adalimumab
Chest infection	SAR	Adalimumab
Probably cutaneous vasculitis	SAR	Adalimumab
Labyrinthitis	SAR	Adalimumab
Acalculic Cholecystitis	SAR	Adalimumab
New onset interstitial lung disease	SAR	Etanercept
Abnormal liver function tests	SUSAR	Rituximab
Gram negative sepsis	SAR	Rituximab
Chest infection	SAR	Rituximab
Neutropaenia	SAR	Rituximab
Chest infection	SAR	Rituximab
Neutropaenia	SAR	Rituximab
Non specific abdominal pain	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 2 nd DIP joint	SAE	
Right hip replacement	SAE	
Admitted for analgesia assessment	SAE	
Laminectomy	SAE	
Pneumonitis	SAE	
® Total knee replacement	SAE	
Asthma	SAE	
Musculoskeletal chest pain	SAE	
Myocardial infarction	SAE	
Grade 2 cancer left breast	SAE	
Rheumatoid arthritis flare up	SAE	
Cerebral infarction left sided hemiparesis+left sided visual/sensory neglect	SAE	
UTI and urinary retention	SAE	
Chest Pain	SAE	
Admitted with lower abdominal pain and vomiting ?bowel obstruction	SAE	
L # NOF	SAE	
Elective admission for decompression and fusion surgery for L4/5	SAE	

Pharmacy update

A new member of staff has now joined the pharmacy team – Pamela Surtees. Welcome! Should you have any queries please contact: 0141 211 8554; and queries/orders can be e-mailed to R&Dimp@ggc.scot.nhs.uk or faxed to 0141 211 2692.

All sites have been contacted with Christmas ordering deadlines for Rituximab supplies. Please let us know if any problems arise over the festive period and we will do our best to help.

Blood Sampling Component.

CENTRAL LAB CHRISTMAS CLOSURE: FROM 22ND DECEMBER TO 2ND JANUARY

EMR Laboratory will be closed from 22nd December to 2nd of January 2013.

This means that there will be no staff in the laboratory at all over this period to handle samples. We ask that samples are **shipped no later than the 19th December** otherwise they will not be processed and will be lost.

- 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

The ORBIT Team would like to take this opportunity to thank you all
for your help and support throughout 2012.

Wishing you all a very Merry Christmas and Happy New Year!



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@glasgow.ac.uk

THANK YOU FOR YOUR SUPPORT IN THE STUDY!

Duncan & Jurgen.