



ORBIT STUDY – NEWSLETTER

Dear all

Welcome to the third edition of the ORBIT newsletter!

The purpose of the newsletter is to provide you with ORBIT updates and will be circulated on an ongoing basis.

Update on approval of sites.

Most of the original sites have been fully initiated and have started recruitment. The last sites are now going through the initiation process and it is envisaged that the “Green for Go” for these sites will be given imminently.

New Sites.

Welcome to our new ORBIT colleagues who kindly volunteered to participate in the study: Poole Hospital (Dr Rahmez Fouz), Ipswich Hospital (Dr Richard Watts), Torbay Hospital (Dr Kirsten Mackay), Derriford Hospital (Dr Mark Perry), West Suffolk Hospital (Dr David O’Reilly), University Hospitals Coventry (Dr Tanya Potter), Royal Devon and Exeter Trust (Dr Richard Haigh). Llandudno Hospital (Dr Yasmeen Ahmad), Royal Cornwall Hospitals Trust (Professor Woolf), South London Healthcare Trust (Dr Louise Dolan), Queens hospital, Essex (Professor Chakravarty) and Basildon and Thurrock University Hospital Trust (Dr Nagui Gendi). All the new sites already have been contacted by Jurgen to set the scene and provide information regarding the study. In addition Elizabeth Douglas (Clinical Trials Pharmacist) will contact the respective pharmacies to conduct pharmacy initiation visits.

For the new sites, we have global permission from CSP (CSP Study ID no. 12570) and the trial has been adopted on to the UKCRN portfolio. All sites need to complete an SSI to gain local NHS approval, and we are working hard to help you with this. Keeping up the pressure on your local R&D department is always important!

Recruitment

Recruitment rate has improved due to the number of sites that have obtained approval and due to the hard work at the participating sites. Thank you! Nonetheless, ARUK is concerned that our recruitment is slipping behind, and have given us a target of 14 participants per month by July 2011 – this is a challenging but achievable target, so please keep up the good work with recruitment. For the sites that have not yet recruited (or recruiting slower than anticipated), either Duncan or Jurgen will make contact to ascertain the reason(s) why.



Please find below the present recruitment rate per site.

Site	Screened	Randomised	Withdrawn
1: Gartnavel General Hospital, Glasgow	11	11	0
2: Glasgow Royal Infirmary, Glasgow	4	3	0
4: Stobhill General Hospital, Glasgow	1	1	0
5: Inverclyde Royal Hospital , Greenock	1	1	0
6: Western General Hospital, Edinburgh	1	1	0
8: Raigmore Hospital, Inverness	4	4	0
9: Wishaw General Hospital, Wishaw	5	5	2
10: Aberdeen Royal Infirmary, Aberdeen	2	2	0
11: Cameron Hospital, Fife	1	0	0
15: Barts and the London NHS Trust, London	4	3	0
16: University of Birmingham	0	0	0
19: Borders General Hospital, Borders	0	0	0
20: Ninewells Hospital, Dundee	1	1	0
Total	35	32	2

Blood sampling procedures.

Thank you for your response to the feasibility carried out to ascertain which sites could undertake a revised sample collection protocol for ORBIT. At present the revised sampling procedures are not yet active; this is because we are awaiting Roche to sign off the necessary contracts. As a result the sampling manual procedure (Version 2.0) is still active.

When the new sampling procedures come into effect you will be notified by Jurgen; in addition additional equipment will be provided on site by Dr Becki Hands.

Temporary suspension of recruitment.

We had a short temporary hiatus in recruitment, following a change in rituximab's SPC, following the EMAs decision not to grant a license extension to allow the use of rituximab in biologic-naïve patients. This allowed us to pause for thought, and conduct a re-evaluation of the risk-benefit of the study through an extensive consultation exercise. There was a broad consensus that the scientific merit and clinical relevance of the trial remain valid.

Summary of Product Characteristics.

The most recent update to the Summary of Product Characteristics (SmPC) for MabThera[®] (rituximab) included the following changes of relevance to the conduct of the ORBIT study for patients with rheumatoid arthritis:

- “Patients should receive treatment with 100mg intravenous methylprednisolone to be **completed** 30 minutes prior to each MabThera infusion to decrease the incidence and severity of infusion reactions.” The current version of the ORBIT protocol (v2.1 dated 03.02.2010) states that patients should receive “methylprednisolone 100mg (30 minutes before rituximab)”

Please review your current practice and ensure that methylprednisolone administration is **completed** 30 minutes before administration of the Rituximab infusion. Any site specific administration or prescription documents should be updated to reflect this change and a copy returned to Jurgen.

A file note indicating the change to the recent SmPC will be sent to all sites that are already initiated for inclusion in the Study Site File to cover this change. For the sites that are awaiting the initiation visit the necessary changes will be made in the Study Site File.

QUERIES.



Should you have any queries then please contact:

- For SSI information please contact Ann on: Ann.Tierney@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.