cromis-2

Clinical Relevance Of Microbleeds In Stroke

UCL

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Recruitment update!

Study I (AF) total recruitment: 872 (target = 1000)

Study II (ICH) total recruitment: 714

Non-anticoagulant related: 538

Anticoagulant related: 176 (target = 300)

Thank you to all centres for recruiting patients to the study.

In this issue

When will recruitment to Study I (AF) and Study II (ICH) end?

The CROMIS-2 grant ends in January 2016.

Recruitment to Study I (AF) will continue to the end of February 2014.

We recruit an average of 45 patients a month, so this should take us to our target of 1000 patients. A no cost extension will be requested to ensure that we have time to analyse all data at 2 years.

Recruitment to Study II (ICH) anticoagulant related ICH arm will continue until the end of October 2014 (as follow up is only 6 months).

We have met our target recruitment for non-anticoagulant related ICH patients and are no longer recruiting to this arm.

Changing your Principal Investigator

My PI is leaving!

Firstly, a suitable replacement must be found. You must contact your Research and Development department and

UK Stroke Forum : Date for your diary

A reminder that the CROMIS-2 team will be at the UK Stroke Forum in Harrogate again this December 2013. We hope to see you all there!

CROMIS-2 Study Update

inform them the current PI is leaving, and who will be taking over as PI at your hospital. Ask for written confirmation that they acknowledge this change to the study management.

Send a copy of this letter to the Co-ordinating Centre for their records.

Ensure the Site File is updated with the new PI's CV, GCP and update the delegation log. Please also send copies to the Co-ordinating Centre for their records.

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New member of the CROMIS-2 team

We are very pleased to welcome our new Clinical Research Fellow to CROMIS-2. Dr Duncan Wilson has taken up the role as Clinical Research Associate for 3 years with the CROMIS-2 team.

Duncan graduated from Otago medical school in 2005 and worked almost exclusively in internal medicine until his move to the UK in 2009.

Since then he has undertaken 3 years in Stroke medicine and 1 year in Neurology. He plans to pursue a career as a vascular neurologist and maintan an arm in research.

Dr Wilson will be involved in MRI quality assurance and analysis, as well as helping sites with eligibility queries and clinical queries.

He will be working alongside our exisiting Clinical Research Fellow, Dr Andreas Charidimou, who remains with us for his final year.

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Storage of data - Document retention times

The guidance from the **MHRA Good Clinical Practice Guide** indicates that if the trial is non-commerical (with no chance of the study drug being submitted for marketing

Meeting:

Wednesday 4th December, 2013, 13.40- 14.20 (lunch time session).

Everyone is welcome to attend!

For further information about the conference, please see their link: http://www.ukstrokeforum.org/

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Publications on our website

We have added our publications to the website, including links to all articles. You can also view these on your mobile device to keep up to date with all the papers we have been publishing.

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Patient follow up

authorisation and being taken to market), the casenotes should be stored for a mimimum of 5 years after the trial has ended. **CROMIS-2 is an observational study so falls into this category.**

If the trial is commercially sponsored the records must be stored for a minimum of 15 years, although this can potentially be extended depending on the commercial status of the drug at that point in time.

General note: Clearly in some cases the casenotes will need to be retained for longer than 5 years/15 years depending on the type of care the patient has received (e.g 30 year requirement for oncology records, 50 year requirement for radiation dose records).

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Proposed new hyperacute stroke study investigating clinical, imaging, and genetic risk factors for ICH following thrombolytic treatment of ischaemic stroke patients

We have received an overwhelming response to our invitation to join us for a new study investigating genetic and clinical risk factors for tissue plasminogen activator pharmacogenomics related ICH. To date, we have received Expressions of Interest (EOI) from 47 UK hospitals, which would protentially allow the participation of nearly 2800 thrombolysed ischaemic stroke patients per year.

We are in the process of preparing grant applications to secure funding for this study. However, we are pleased to say that there is still time for other centres to take part in this study if you have not yet returned an EOI form.

If you have any questions about this exciting new study, please contact the Lead Investigator, Dr Bartosz Karaszewski bartosz.karaszewski@mail.com

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Anonymised MRI and CT scans

A reminder that they MUST be anonymised without encryption or passwords. We cannot open

Please remember to complete any outstanding follow ups by telephone if the Co-ordinating Centre has not been able to receive the forms in the post.

If overdue, the form will be **highlighted in red** in your eCRF data report.

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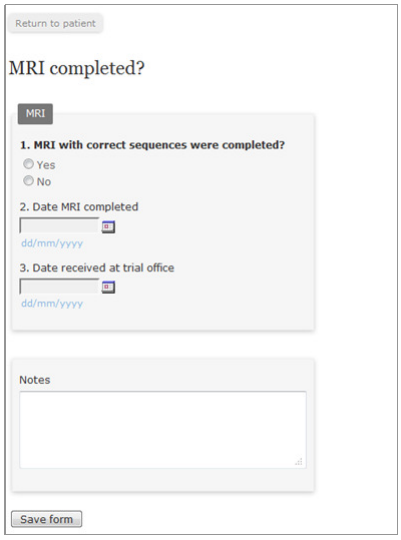
MRI completion e-forms



We have added a new page to the electronic CRF, confirming whether an MRI scan (or CT scan) was completed.

We aim to transfer the dates received at the Co-ordinating Centre for all past patients, but bear with us as we have over 1500 to do!

This will help us keep track of when scans were completed/sent /received, and whether they pass the quality assurance check. **We can only reimburse scans if the FULL CROMIS-2 MRI PROTOCOL is completed within the accepted parametres.**

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A big thank you to all our sites for such fantastic recruitment!

encrypted CDs and they do not need passwords if they are fully and appropriately anonymised as per protocol.

If we receive a scan with missing sequences, our clinical team will raise an electronic query and send to everyone in your team when they have quality assured the scan.

To save time and addtional work by the clinical team and yourselves, please check the sequences are on each scan before sending, and check there is no password and/or encryption.

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Keep up the good work!

The CROMIS-2 team - Clare, David, Andreas and Duncan

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