ASAP Newsletter

Issue 4 March 2014

ADJUVANT STEROIDS IN ADULTS WITH PANDEMIC INFLUENZA

NIHR CRN Portfolio ID: 15318

Following the request by the Ethics Committee to amend our study documentation to obtain written consent prior to enrolment, a substantial amendment was submitted to the Ethics Committee last month. This has now received approval, enabling us to progress with the setting up of sites for the trial. The trial protocol now stipulates that written consent will be sought from participants that have the capacity to consent using a short one page combined patient information sheet and consent form.

Study-wide checks conducted by the lead CLRN are expected to be completed within the next couple of days.

Establishing a 'Core' ASAP team

The NCTU will perform regular checks on the trial and sites during the hibernation phase to ensure that the trial is maintained in a 'ready-to-go' state at all times.

In order to aid this process, we request that a 'core' team is identified at each site with whom the NCTU will communicate about the trial during the hibernation phase. This should comprise (as a minimum) of the Principal Investigator, Research Nurse/Trial Coordinator and Pharmacist.

Members of this 'core' team will be expected to be GCP trained and maintained on the delegation log throughout the set-up and hibernation phases. Any changes should be communicated to the Trial Manager

NEXT STEPS IN SETTING-UP SITES

For those sites that have returned both the site feasibility and pharmacy questionnaires we will now begin to progress towards obtaining NHS site permissions in the following way:

- We will work to resolve any outstanding queries on study conduct identified from the questionnaires and select sites that meet all requirements for study conduct, ensuring wide geographical spread.
- SSIs to be transferred to selected sites for completion
- Identification of a 'core' team that will oversee/maintain the trial during the hibernation phase until activation (see note opposite)
    - Please send Trial Manager GCP certificates and CVs for core team members

SITE FILES

- Investigator Site Files will be sent from NCTU to site
- A Pharmacy Manual will be e-mailed to the trial Pharmacist
    - Pharmacy File may be set-up in accordance with local templates.
- Many of the documents will be watermarked as draft since these will be reviewed throughout the hibernation phase. Final versions will only be provided when the trial is activated.

Contact Details

Trial Manager—Clare Brittain

✉ asap@nottingham.ac.uk

☎ 0115 884 4952

Chief Investigator—Dr Wei Shen Lim

✉ weishen.lim@nuh.nhs.uk

☎ 0115 9691169 ext 59347

ASAP website

http://nuhrise.org/the-asap-trial or type 'ASAP Flu Trial' into Google.

Training of Site Staff

The majority of training will be conducted once the decision has been made to activate the trial in a pandemic.

The Trial Management Group are working with GCP facilitators to develop a suitable online training package for clinical staff that covers the re-quired elements of GCP to conduct the trial at site.

In addition, a training package for pharmacy staff and staff completing the CRFs will be rolled out prior to recruitment commencing.

NOTTINGHAM CLINICAL TRIALS UNIT

This project was funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme (project number 11/46/14) and will be published in full in Health Technology Assessment. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health.