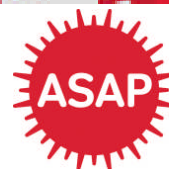


ASAP Newsletter

Issue 1, August 2013

NIHR CSP ID: 108256



ADJUVANT STEROIDS
IN ADULTS WITH
PANDEMIC INFLUENZA

Welcome to the first ASAP Trial Newsletter!

We are pleased to report that the trial protocol has now been finalised and all trial documents have now been submitted to the Ethics Committee. These will be considered for approval at their meeting on 27th September 2013. We are aiming to submit the trial to the MHRA within the next month and hope to have both approvals in place by the Autumn. A major consideration in the design of the trial has been the practicalities of trying to obtain consent from patients in a pandemic situation when NHS resources are stretched to the limit. Thus, the trial has been designed with simplicity in mind to ensure the delivery of the trial has minimal impact on normal clinical service during a pandemic.

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ASAP website

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

Frequently asked questions (FAQs)

A FAQs document is current being produced with answers to the most commonly raised questions. This will be circulated soon and placed on the trial website.

Consent in pandemic research

Lack of staff resources was identified as a major barrier to conducting a clinical trial in the 2009 pandemic with the process of informed consent being a major consideration. We have been consulting with various Patient & Public Involvement Groups as well as members of the general public to explore the options for obtaining consent for the ASAP trial in a pandemic situation. Following these consultations, the following model has been submitted for approval by the ethics committee:

Trial news

Participating sites—selection

- Approx. 50 sites will be set-up to run the trial ensuring UK-wide coverage
- Site selection and pharmacy questionnaires have been sent to all sites that have expressed an interest so far - **many thanks to the following sites that have already sent both of these back:**

Countess of Chester Hospital

Norfolk & Norwich University Hospital

Royal Derby Hospital

Wythenshawe Hospital

King's Mill Hospital

Queen Alexandra Hospital, Cosham

St James' University Hospital

York Hospital

- We are currently in the process of reviewing the returned questionnaires
- The delivery of the ASAP trial at your hospital may involve collaboration with a number of specialities (such as Emergency Medicine, Respiratory, Acute Medicine, Infectious Diseases and Critical Care). Early discussion and involvement with relevant specialities is encouraged when completing the site selection questionnaires.
- **Further sites still needed—please contact the Trial Manager**

Trial Steering Committee (TSC) Meeting

The first TSC meeting was held on 28th June 2013. The TSC have approved the protocol version submitted to the ethics committee for review.

VERBAL
CONSENT

DEFERRED
WRITTEN
CONSENT

- At point of hospital admission
- Patient information sheet for verbal consent used to guide discussions
- Approx 5 mins
- Consent decision documented **by doctor** in patient's medical notes
- Full information sheet given to read later

- Obtained prior to discharge from hospital
- Informed consent form signed and dated

NOTTINGHAM
CLINICAL
TRIALS
UNIT