ADJUVANT STEROIDS IN ADULTS WITH PANDEMIC INFLUENZA

Patient Information Sheet and Consent

The ASAP (Steroids in Adults with Pandemic Influenza) Trial

Does taking a steroid help improve recovery from pandemic flu?
You have been admitted to hospital with influenza-like illness and need urgent care. You will get all the usual treatment for influenza-like illness that we provide at this hospital. As well as this, we would like to include you in a research study to see if a steroid called dexamethasone helps patients hospitalised with pandemic flu. Some studies have shown that this drug improves the outcome in patients with pneumonia or severe 'blood poisoning'. We do not know if this drug will help with pandemic flu so we are doing this study.

If you agree to take part in the study you will be given study medicine to take for 5 days. This is a liquid and you will take 15ml (about 3 teaspoons) orally once a day. If your standard treatment needs to be given via a feeding tube then the study medicine will also be given to you via the feeding tube. The study medicine will be given in addition to the normal treatment given to patients with flu.

The study medicine will contain either dexamethasone or placebo. Placebo is a dummy medicine containing no active ingredients. Which treatment you receive is determined by chance (i.e. at random). Neither you nor any of the doctors or nurses looking after you will know which treatment you are receiving. Using a placebo helps us to make a fair test between treatments.

Steroids such as dexamethasone are very commonly used drugs. When given for a short time, as in this study, steroids are generally considered safe with few side-effects. If the doctor looking after you feels you should not receive steroids, you will not be eligible to take part in this study.

We will need to collect some information from your medical notes about your stay in hospital and will send this to a central office in Nottingham. We will also send them your contact details and your NHS number so that they can find out how you are doing after you have left hospital and send you a short 5 minute questionnaire to complete one month after you go home from hospital. If you agree to participate in the study your GP will also be informed.

If you want to know more about our study now then we will tell you. But otherwise we will give you an information leaflet to read at a later time which tells you everything you need to know. You do not have to take part and you may change your mind at any time; please just tell your doctor or nurse.

This study has been approved by the South Central – Oxford C Research Ethics Committee (REC).

I confirm that I have been given a copy of the Patient Information Leaflet (version 2.0, dated 11-Feb-2014) and I agree to participate in the ASAP study; for my medical records to be accessed, my GP informed and my contact details and NHS number collected and used for the purpose of the study.

Name of participant	Signature	Date
Name of person taking consent	Signature	Date

Participant ID number when allocated: ☐☐☐☐☐ NHS or Hospital No. _____

ADJUVANT STEROIDS IN ADULTS WITH PANDEMIC INFLUENZA

Personal Legal Representative* Information Sheet & Consent

*May be a partner, relative or friend

The ASAP (Steroids in Adults with Pandemic Influenza) Trial

Does taking a steroid help improve recovery from pandemic flu?
Your partner/relative/friend has been admitted to hospital with influenza-like illness and needs urgent care. They will get all the usual treatment for influenza-like illness that we provide at this hospital. As well as this, we would like to include them in a research study to see if a steroid called dexamethasone helps patients hospitalised with pandemic flu. Some studies have shown that this drug improves the outcome in patients with pneumonia or severe 'blood poisoning'. We do not know if this drug will help with pandemic flu so we are doing this study.

If you agree for your partner/relative/friend to take part in the study they will be given study medicine to take for 5 days. This is a liquid and they will take 15ml (about 3 teaspoons) orally once a day. If their standard treatment needs to be given via a feeding tube then the study medicine will also be given to them via the feeding tube. The study medicine will be given in addition to the normal treatment given to patients with flu.

The study medicine will contain either dexamethasone or placebo. Placebo is a dummy medicine containing no active ingredients. Which treatment they receive is determined by chance (i.e.at random). Neither you nor any of the doctors or nurses looking after them will know which treatment they are receiving. Using a placebo helps us to make a fair test between treatments.

Steroids such as dexamethasone are very commonly used drugs. When given for a short time, as in this study, steroids are generally considered safe with few side-effects. If the doctor looking after your partner/relative/friend feels they should not receive steroids, they will not be eligible to take part in this study.

We will need to collect some information from your partner/relative/friend's medical notes about their stay in hospital and will send this to a central office in Nottingham. We will also send their contact details (we may also send your contact details as well) and NHS number so that they can find out how your partner/relative/friend is doing after they leave hospital and a send a short 5 minute questionnaire to complete one month after they go home from hospital. We will also inform their GP.

If you want to know more about our study now then we will tell you. But otherwise we will give you an information leaflet to read at a later time which tells you everything you need to know. Your partner/relative/friend does not have to take part and you/they may change your/their mind at any time; please tell their doctor or nurse if there is a change of mind.

This study has been approved by the South Central – Oxford C Research Ethics Committee (REC).

I confirm that I have been given a copy of the Personal Legal Representative Information Leaflet (version 2.0, dated 11-Feb-2014) and I agree for them to participate in the ASAP study; for their medical records to be accessed, their GP informed and contact details and NHS number collected and used for the purpose of the study.

Name of person giving consent	Signature	Date

Relationship to participant: _____ Name of participant: _____

Name of person taking consent	Signature	Date

Participant ID number when allocated: ☐☐☐☐☐ NHS or Hospital No. _____