

### *What if there is a problem?*

If you have a concern or questions about any aspect of this study you should speak to your local study team who will do their best to answer your questions or you can contact the Patient Advice and Liaison Service (PALS); contact details can be found on the back of this leaflet

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.

In the event that something does go wrong and you are harmed during the study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

### *Will my taking part be kept confidential?*

All information we collect about you will be kept in the strictest confidence. Only persons involved in the conduct or regulation of the study will have access to your personal details. We will also register your NHS number with the Health and Social Care Information Centre to help us follow up your health status. We will have confidentiality and security arrangements in place to ensure your details are dealt with in the strictest confidence. These details will be kept securely, with access restricted. You will not be named or otherwise identified in any study publication.

We will let your GP know that you are taking part in the study.

*The ASAP trial is funded by the National Institute for Health Research (NIHR)*

## QUESTIONS OR CONCERNS?

If you would like more information, or have any concerns about the study please contact your local research team:



### *Who has reviewed the study?*

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed by the South Central—Oxford C Research Ethics Committee.



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ADJUVANT STEROIDS  
IN ADULTS WITH  
PANDEMIC INFLUENZA

## Patient Information

### Leaflet



## Information about the ASAP study

## **Admitted to hospital with flu?**

*We would like to invite you to take part in our research study.*



### **What is the purpose of the study?**

Some studies have shown that a steroid drug called dexamethasone improves the outcome in patients with pneumonia or severe 'blood poisoning'. There is uncertainty whether this drug might also improve the recovery of patients with severe flu infection. In this study we are trying to find out whether dexamethasone given for 5 days in addition to the normal treatment for flu is beneficial in patients admitted to hospital with flu during a pandemic.

**We are asking up to 2200 patients admitted to hospital with a flu-like illness to take part.**

### **What will I have to do?**

If you decide to take part in the study you will be given some study medicine to take once a day for 5 days.

The study medicine will contain either:

- 1) dexamethasone or
- 2) a placebo (a dummy treatment which looks like the real medicine but contains no active ingredient.)

Using a placebo helps us make a fair comparison of the treatments. Neither you nor any of the doctors or nurses looking after you will know which treatment you are receiving (although if they need to find out they can do so). The decision about which treatment you receive will be decided by chance (rather like tossing a coin) and neither you nor your doctor will be able to choose. This is important as it ensures a fair comparison between treatments.

At the end of the study, we will be able to compare if patients who took dexamethasone did better compared to patients who took placebo.

**In all instances, you will still receive the standard treatment currently used to treat patients with a flu-like illness.**

### **About the study medicine**

The study medicine is a liquid. You will be given a bottle containing enough medicine to last for 5 days. You will need to take 15ml by mouth once a day for 5 days. If you are too poorly to take your standard treatment by mouth, doctors may use a feeding tube to give you treatment directly to your stomach. If this happens, the feeding tube will also be used to give the study medicine.

Your doctor will explain how to take your medicine and you need to do this for 5 days. If you leave hospital then you will take the medicine home to continue it at home. You should continue to take your medicine as your doctor tells you to.

### **What information is collected?**

We want to look in your medical notes for information about your illness and the treatment your doctor gives you whilst in hospital. Your doctor will give this to us with your permission.

We would like to find out how you are doing one month after you leave hospital. We will send you a short questionnaire; this will take about 5 minutes to complete. The questionnaire will be posted to you at your home, with a freepost return envelope. Your contact details will be collected and sent to the Coordinating Centre in Nottingham for this purpose. If we do not hear from you after a time, we will attempt to contact you by telephone to find out if you have received the questionnaire and how you are doing.

### **Possible disadvantages/risks**

Steroids are very commonly used drugs. Side effects can include increased appetite, acne, mood changes such as becoming very aggressive, irritable and short tempered with people and rapid mood swings, such as feeling very happy one minute and sad and weepy the next. These are very rare. Scientific studies (trials) of steroids in pneumonia and blood poisoning have shown improved outcomes with steroids (patients less likely to die and reduced length of hospital stay) without any associated major harmful effects. Less reliable studies conducted during the 2009 pandemic have shown mixed results—in some studies patients who received steroids were more likely to die and in other studies patients were no more likely to die, compared to patients who did not receive steroids.

### **Possible benefits**

We cannot promise that the study will help you, but the information that we get from the study might help improve the treatment of patients with pandemic flu in the future.

### **What happens after the study?**

When you have finished your study medicine you will receive normal care whilst in hospital. If you have left hospital at this point you will not have to do anything. We will contact you with a questionnaire one month after you leave hospital.

### **Results of the study**

The results of the study will be available after it has finished and will usually be published in a scientific journal and be presented at a scientific conference. However, you will not be identified in any report or publication. A summary of the results will also be sent to you.