ADJUVANT STEROIDS IN ADULTS WITH PANDEMIC INFLUENZA

CLINICAL TRIAL PARTICIPANT

Patient Transfer Pack

Final Version 1.0 15 August 2017

Important Information Enclosed

This patient has given their consent to participate in the ASAP clinical trial.

This pack contains everything required in order to ensure the patient's continued participation in the trial.

Participant Information – *to be completed by randomising (host) hospital*	
Initials	☐☐☐
Date of Birth	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY
ASAP Trial ID number	☐☐☐☐☐
NHS number	☐☐☐ ☐☐☐ ☐☐☐☐

Initials | | | | ASAP Trial ID | | | | | |

Contents

The following will also accompany the patient:

1. Copy of signed one page Information Sheet and Informed Consent Form
2. Any Remaining study drug

Note to receiving hospital – if any of the above listed documents are missing, please visit www.asaptrial.org or contact either the Trial Coordinating Centre (see **section 3**) or the randomising hospital (see **section 7**).

A copy of the full ASAP trial protocol can be found at www.asaptrial.org

Initials | | | | ASAP Trial ID | | | | | |

1. INSTRUCTIONS FOR RANDOMISING (HOST) HOSPITAL *(THIS IS THE HOSPITAL WHICH THE PATIENT IS BEING TRANSFERRED FROM):*

The randomising hospital retains overall responsibility for its trial participants. In order to facilitate the ongoing participation of a trial participant who is being transferred it is important that the relevant sections of this Patient Transfer Pack are completed in full.

The randomising hospital should ensure that the participant's details are completed on the cover sheet and in the space provided in the header on each page. The randomising hospital should also complete **section 7** and **section 8** of this Transfer Pack.

Once all relevant sections have been completed, please ensure that the following are included in the Transfer Pack and accompany the participant (please tick ✓ to confirm included):

- Copy of signed one page Information Sheet and Informed Consent Form ☐
- Remaining study drug ☐

After the participant has been transferred, it is the responsibility of the randomising hospital to obtain outstanding trial data from the receiving hospital and ensure that the Case Report Form (CRF) is completed.

Patient Transfer Pack prepared by:

Name _____

Job Title _____

Signature _____

Initials | | | | ASAP Trial ID | | | | | |

2. INSTRUCTIONS FOR RECEIVING HOSPITAL *(THIS IS THE HOSPITAL WHICH THE PATIENT HAS BEEN TRANSFERRED TO):*

You have received this information because a participant in the ASAP pandemic flu trial has been transferred into your care. We ask that you assist in ensuring that the patient's participation in the trial continues. This pack should contain everything you need.

The information given in **section 6** of this pack details the number of remaining doses of study drug that the participant has remaining.

For participants who have been transferred to your hospital and have not yet completed their course of study drug, the participant should receive a 15ml dose of study drug each day for the number of doses remaining (outlined in **section 6**). Further doses should ideally be given each morning so that there are approximately 24 hours between doses.

The randomising hospital is responsible for ensuring that all trial data are obtained, and will therefore contact you in order to acquire any outstanding follow-up information.

Data you will be asked for will include:

- Number of doses of study drug administered
- Discharge information *(if applicable)*
- Hospital transfers *(if applicable)*
- Re-admissions *(if applicable)*
- ICU admissions *(if applicable)*
- Death *(if applicable)*

Should you need further information or documentation, please visit www.asaptrial.org or contact the Trial Coordinating Centre (see **section 3**).

SUMMARY OF Actions required:

- Give trial medication to patient (total 5 days) – see Section 6 for number of doses remaining.
- Expect call from randomising hospital for data collection in about 4 weeks' time.
- Contact Trial coordinating centre if there are any queries. (contact details in Section 3)

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3. CONTACT INFORMATION FOR TRIAL COORDINATING CENTRE – IF YOU HAVE ANY QUERIES REGARDING THE CONDUCT OF THE ASAP TRIAL, PLEASE CONTACT THE COORDINATING CENTRE

Coordinating Centre	Nottingham Clinical Trials Unit Nottingham Health Science Partners C Floor, South Block Queen's Medical Centre Nottingham NG7 2UH
Trial Management Team	✉ asap@nottingham.ac.uk ☎ +44 (0) 115 82 31587

Initials | | | | ASAP Trial ID | | | | | |

4. KEY TRIAL INFORMATION

Title	Double-blinded randomised controlled trial of early low dose steroids in patients admitted to hospital with influenza during a pandemic
Design	Randomised, placebo-controlled
Aims	To determine whether a 5-day course of dexamethasone, compared to placebo, started within 24 hours of admission to hospital, <u>in addition to standard care is:</u> 1) Associated with a lower risk of death or admission to intensive care compared to placebo **(PRIMARY OBJECTIVE)** 2) Associated with: a) a reduction in length of hospital stay b) the frequency of hospital readmission and/or the frequency of GP consultations after discharge **(SECONDARY OBJECTIVES)**
Intervention	• 15ml dexamethasone (6mg) once daily for 5 days started within 24 hours of admission to hospital (dose approximately equivalent to prednisolone 40 mg daily for 5 days) • 15ml placebo once daily for 5 days started within 24 hours of admission to hospital
Outcome measures	**<u>PRIMARY</u>** Admission to intensive care unit or death, within 30 days of admission **<u>SECONDARY</u>** 1. Length of stay in intensive care unit 2. Readmission within 30 days of hospital discharge 3. GP consultations within 30 days of hospital discharge 4. Length of stay in hospital 5. Death within 30 days of admission to hospital 6. Admission to intensive care unit within 30 days of admission to hospital The full statistical plan includes the flexibility to allow for pandemics of different severity.
Population	Adults (≥16 years old) hospitalised with an influenza-like illness during a pandemic.
Eligibility	• Aged ≥ 16 years • Admitted to hospital within the previous 24 hours with a clinical diagnosis of an influenza-like illness • Have given consent Exclusion criteria are: • Known to be taking oral or IV corticosteroid treatment • Require treatment with oral or IV corticosteroids upon admission to hospital as standard treatment for comorbid illness • Known to be on insulin or oral medication for the treatment of diabetes mellitus • Known contra-indication to dexamethasone or any of the excipients (refer to current version of SPC)
Duration	Recruitment is expected to last about 6 weeks.

Initials ☐☐☐ ASAP Trial ID ☐☐☐☐☐

5. RANDOMISING INFORMATION

The study medication for this trial is dexamethasone or placebo. This is provided as a 75ml bottle sufficient for 5 days' supply only.

This patient has been randomised to receive one of the below trial interventions:

1. 15ml dexamethasone (6mg) once daily for 5 days started within 24 hours of admission to hospital (dose approximately equivalent to prednisolone 40 mg daily for 5 days)
2. 15ml placebo once daily for 5 days started within 24 hours of admission to hospital

6. PARTICIPANT DOSAGE INFORMATION - TO BE COMPLETED BY RANDOMISING (HOST) HOSPITAL

Number of days of study drug remaining ***Note – if there are any doses of study drug remaining then a bottle of ASAP trial study drug should be accompanying the patient. It is crucial to the success of the ASAP trial that any remaining doses of study drug are administered as per protocol.***	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Date of last dose of study medication:	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY
Time of last dose of study medication:	☐☐ : ☐☐ Unknown ☐ 24 Hr Clock - HH:MM

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7. CONTACT INFORMATION FOR RANDOMISING (HOST) HOSPITAL – TO BE COMPLETED BY RANDOMISING (HOST) HOSPITAL

Hospital Address	
Principal Investigator	Name ✉ ☎
Research Nurse	Name ✉ ☎
Pharmacist	Name ✉ ☎

8. GUIDANCE ON SERIOUS ADVERSE EVENT REPORTING

A serious adverse event is any untoward medical occurrence in a patient administered a medicinal product, which does not necessarily have to have a causal relationship with the treatment (the study medication) that at any dose:

- Results in death,
- Is life-threatening (NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.)
- Requires inpatient hospitalisation or prolongation of existing hospitalisation,
- Results in persistent or significant disability/incapacity, or
- Is a congenital anomaly/birth defect.
- Other important medical events (NOTE: Other events that may not result in death are not life threatening, or do not require hospitalisation, may be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.)

Should an ASAP trial participant experience a Serious Adverse Event, this should be reported to the randomising hospital as soon as possible. See section 7 for contact details for the randomising hospital. The randomising hospital should determine whether the SAE they have received details for requires reporting to NCTU, as per guidance in the trial protocol.