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Adjuvant Steroids in Adults with Pandemic influenza

Submission date 11/10/2013	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 11/10/2013	**Overall study status** Stopped	
Last Edited 16/11/2022	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
The study is trying to find out whether a steroid drug called dexamethasone can help patients hospitalised with flu during a pandemic. Flu pandemics occur when a new flu virus emerges meaning that very few people have any protection against the virus. The new virus can therefore spread easily and cause serious illness. During a pandemic it is expected that many millions of people around the world will become ill. Some studies have shown that a steroid drug called dexamethasone helps people with pneumonia or severe 'blood poisoning' and we think that it may also help patients with pandemic flu but we are not sure. We are therefore trying to find out whether this treatment, given in addition to the normal flu treatment, will help adults who are admitted to hospital with pandemic flu to recover.

Who can participate?
Adults (aged 16 years and above) who are admitted to hospital with flu-like symptoms during a pandemic will be asked to take part in the study. We are aiming to recruit 2200 patients.

What does the study involve?
Patients will be randomly allocated to receive either dexamethasone or placebo (a 'dummy' treatment which looks like the real medicine but contains no active ingredient). Patients who take part will be given study medication to take once a day for 5 days. Using a placebo helps us to make a fair comparison of the treatment. The study medication will be given by mouth. For patients that are too poorly to take medication by mouth, the doctor may use a feeding tube to give medicines directly into the stomach. The study medication can be given in the same way. As well as the study medication, all patients will also receive the usual treatment given to patients with a flu-like illness.

What are the possible benefits and risks of participating?
Steroids are very commonly used drugs. Side effects can include increased appetite, acne, mood changes, such as feeling very happy one minute and then very sad and weepy the next. Mood changes are very rare. Scientific studies of steroids in pneumonia and 'blood poisoning' have not found any major harmful effects from steroids. Less reliable studies have shown mixed results - some showed that patients who received steroids in the 2009 flu pandemic were less likely to die, other studies showed patients were more likely to die and yet others studies showed

patients were not more likely to die, compared to patients who did not receive steroids. We cannot promise that the treatment will help, but the information that we get from the study might help improve the treatment of patients with pandemic flu in the second and third pandemic waves. This information should be applicable to patients around the world.

Where is the study run from?
The study will take place in several hospitals throughout the United Kingdom. However we will only know which hospitals will be involved for certain once we know which areas are most affected by the pandemic. The study is being co-ordinated by the Nottingham Clinical Trials Unit.

When is the study starting and how long is it expected to run for?
Once all approvals have been obtained the study will be placed in 'hibernation' until the study is activated during a flu pandemic.

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mr Garry Meakin
asap@nottingham.ac.uk

Study website
https://www.nctu.ac.uk/studies/current-studies/asap.aspx

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2013-001051-12

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15318; HTA 11/46/14

Study information

Scientific Title
Early low-dose steroids for adults admitted to hospital with influenza-like illness during a pandemic: a randomised placebo controlled trial

Acronym
ASAP

Study objectives
During a pandemic, influenza infection can be severe because the population has little or no immune protection to the new virus. In such circumstances, severe influenza may lead to hospitalisation, admission to intensive care or death. A pandemic also poses challenges for health care systems which may be overstretched leading to further detrimental impacts on patient care. Current treatment options for influenza, including antivirals, are only partly effective at reducing adverse outcomes. Clinical trials of corticosteroids in patients with pneumonia or severe 'blood poisoning' have reported improved outcomes. There is uncertainty whether corticosteroids might also improve the recovery of patients with severe influenza infection. The ASAP trial will investigate whether low-dose corticosteroids (dexamethasone 6 mg once a day for 5 days) given to adults (aged 16 years and over) within 24 hours of admission to hospital with an influenza-like illness in addition to standard treatment are beneficial.

The influenza pandemics of the last century have typically spread in 2 or more waves, each wave approximately of 6 weeks duration. Therefore, we aim to complete recruitment (2200 patients) within a 6 week period corresponding to the first pandemic wave in order to inform pandemic management before the subsequent waves strike.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/114614
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0008/81773/PRO-11-46-14.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford C, 19/02/2014, 13/SC/0436

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet'

Health condition(s) or problem(s) studied
Influenza

Interventions
Dexamethasone vs placebo, Participants will be randomised to receive either dexamethasone 6 mg once daily for 5 days or placebo once daily for 5 days.

The planned sample size of 2200 patients is based on a high-severity pandemic along a range of possible scenarios. The outcome measures described relate to a high-severity pandemic, however the full statistical analyasis plan includes the flexibility to alllow for pandemics of different severity.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Dexamethasone

Primary outcome measure
Admission to intensive care unit or death, within 30 days of admission to hospital

Secondary outcome measures
1. Admission to intensive care unit within 30 days of admission to hospital
2. Death within 30 days of admission to hospital
3. GP consultations within 30 days of hospital discharge
4. Length of stay in hopsital
5. Length of stay in intensive care unit
6. Readmission to hospital within 30 days of hospital discharge

Overall study start date
01/08/2013

Completion date
01/05/2025

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
This trial will be activated in the event of a pandemic. Trial activation will be decided by the NIHR in close discussion with the Trial Steering Committee, the Chief Investigators of the eight NIHR Pandemic Portfolio studies and the Department of Health. The following inclusion criteria will apply when the trial is activated:
During an influenza pandemic, patients are eligible for the entry into the trial if they:
1. Are aged ≥ 16 years
2. Have been admitted to hospital within the previous 24 hours with a clinical diagnosis of an influenza-like illness
3. Have given consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 2200

Key exclusion criteria
Patients are not eligible for the study if ANY of the following apply at the time of admission to hospital:
1. Known to be taking oral or intravenous corticosteroid treatment
2. Require treatment with oral or intravenous corticosteroids upon admission to hospital as standard treatment for comorbid illness.
3. Known to be on insulin or oral medication for the treatment of diabetes mellitus
4. Known contra-indication to dexamethasone or any of the excipients

Date of first enrolment
01/08/2018

Date of final enrolment
01/05/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Nottingham Clinical Trials Unit
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

Sponsor details
Queens Medical Centre
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

Website
https://www.nuh.nhs.uk/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/02/2015		Yes	No
Other publications	Simulated activation of study	16/11/2017	16/11/2022	Yes	No
HRA research summary			28/06/2023	No	No