Blinded randomised controlled trial of low-dose Adjuvant Steroids in Adults admitted to hospital with Pandemic influenza (ASAP): a trial ‘in hibernation’, ready for rapid activation

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Plain English summary

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Plain English summary

The aims of this study are to (1) find out whether a commonly used steroid (a medicine that reduces inflammation) called dexamethasone, given in addition to the normal treatment for flu, will benefit patients admitted to hospital with flu during a pandemic and (2) set up a trial in advance of a pandemic, which can be put into ‘hibernation’ for rapid activation when required.

The trial will be conducted at approximately 40 hospitals in the UK. Adults admitted with flu in a pandemic will be asked to take part. Participants will be randomly given either a 5-day course of dexamethasone or a matching placebo (dummy medicine without any active ingredients). Information recorded routinely in patients’ medical notes will be used to determine whether or not treatment with dexamethasone reduces the number of patients who die or are admitted to intensive care within 30 days of hospital admission.

The challenges encountered during set-up included:

(a) planning for a period when health-care resources will be exceptionally stretched
(b) ensuring geographical spread of participating hospitals
(c) addressing future training needs of investigators
(d) resilience planning of trial management.

Patients and the public were found to prefer arrangements for giving their consent which current regulations do not permit. Whether or not this will create difficulties in future remains to be determined.

This study demonstrates that advance set-up of a trial with full regulatory approvals in place, is possible; it serves as a model for the development of other ‘off-the-shelf’ trials in public health emergencies.
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