

# 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

Wei Shen Lim,<sup>1\*</sup> Clare Brittain,<sup>2</sup> Lelia Duley,<sup>2</sup> Sheila Edwards,<sup>3</sup> Stephen Gordon,<sup>4</sup> Alan Montgomery,<sup>2</sup> Jonathan Nguyen-Van-Tam,<sup>5</sup> Robert Read,<sup>6</sup> Diane Whitham,<sup>2</sup> David Whynes,<sup>7</sup> Mark Woodhead<sup>8</sup> and Dan Wootton<sup>9</sup>

<sup>1</sup>Respiratory Medicine, Nottingham University Hospitals NHS Trust, Nottingham, UK

<sup>2</sup>Nottingham Clinical Trials Unit, University of Nottingham, Nottingham, UK

<sup>3</sup>British Thoracic Society, London, UK

<sup>4</sup>School of Tropical Medicine, Liverpool School of Tropical Medicine, Liverpool, UK

<sup>5</sup>Division of Epidemiology and Public Health, University of Nottingham, Nottingham, UK

<sup>6</sup>Faculty of Medicine, University of Southampton, Southampton, UK

<sup>7</sup>School of Economics, University of Nottingham, Nottingham, UK

<sup>8</sup>Respiratory Medicine, Central Manchester University Hospitals NHS Foundation Trust, Manchester, UK

<sup>9</sup>Institute of Infection and Global Health, University of Liverpool, Liverpool, UK

\*Corresponding author

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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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## This report

The research reported in this issue of the journal was funded by the HTA programme as project number 11/46/14. The contractual start date was in December 2012. The report detailing the set up phase and initial outcomes began editorial review in November 2014 and was accepted for publication in January 2015. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report. Should the study progress further, the full report will be published in the HTA journal.

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