ISRCTN44137563 https://doi.org/10.1186/ISRCTN44137563

Maternal and perinatal outcomes of pandemic influenza in pregnancy

Submission date	Recruitment status	[ ] Prospectively registered
21/01/2013	Stopped	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/01/2013	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/01/2023	Respiratory	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Evidence from the last influenza pandemic in 2009 showed that pregnant women were particularly vulnerable to severe infection. The aims of this study are, in a future influenza pandemic, to estimate the incidence of hospitalisation with pandemic-type influenza in pregnancy, and to describe the outcomes of pregnancy particularly in relation to specific treatments and according to whether women have received influenza immunisation.

Who can participate?
Women with influenza in pregnancy in a future pandemic

What does the study involve?
This study collects anonymous data only. The cohort of pregnant women infected with influenza are identified through the UK Obstetric Surveillance System (UKOSS) network of nominated reporting clinicians in each consultant maternity unit in the UK. Doctors and midwives are asked to report anonymous details of pregnant women with confirmed pandemic influenza admitted to their unit. Each month throughout the study, the information collected is analysed to describe the pregnancy and other outcomes for women and their babies and to describe their treatment. These data are compared with previously collected information about women who do not have influenza in pregnancy. These analyses are used to develop guidance for prevention and treatment during the pandemic.

What are the possible benefits and risks of participating?
There is no benefit to individual women of inclusion of their anonymous data in the study. However, the information is used to improve care for women and babies in the future. This study collects anonymous data only, after women have been admitted to hospital and treated. There are thus no risks to participants.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
The study was funded in 2012, but will only be activated in the event that there is a new influenza pandemic

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

Who is the main contact?
Prof. Marian Knight
marian.knight@npeu.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Marian Knight

Contact details
National Perinatal Epidemiology Unit
University of Oxford
Old Road Campus
Oxford
United Kingdom
OX3 7LF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/46/12, Version 3 12/09/12

Study information

Scientific Title
Maternal and perinatal outcomes of pandemic influenza in pregnancy: a cohort study

Study objectives
The hypothesis of this study is that in a future influenza pandemic, pregnant women will be at increased risk of poor maternal and pregnancy outcomes, and a rapid study of this susceptible group will be important to inform both ongoing preventive and management policies.

Further details of the UK-wide Obstetric Surveillance System (UKOSS) which will be used to collect these data can be found on www.npeu.ox.ac.uk/ukoss

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Nottingham, 11/09/2012, ref: 12/EM/0365

Study design
Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
There is no participant information sheet for this study as it uses anonymous data only

Health condition(s) or problem(s) studied
Pandemic influenza in pregnancy

Interventions
Observational study of pregnancy outcomes in women hospitalised with the pandemic influenza. Outcomes following extra corporeal membrane oxygenation (ECMO) and influenza immunisation will be described.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Incidence of hospitalisation with pandemic influenza in pregnancy

Secondary outcome measures
1. Maternal death
2. Level 3 critical care unit admission
3. Other major complication
4. Preterm birth
5. Congenital anomaly
6. Stillbirth
7. Early neonatal death
8. Perinatal death

Overall study start date
01/06/2012

Completion date
31/12/2020

Reason abandoned (if study stopped)
Study redesigned and relaunched for COVID pandemic (see ISRCTN40092247)

Eligibility

Key inclusion criteria
All pregnant women in the UK admitted to hospital with confirmed pandemic influenza

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
500

Key exclusion criteria
Women not meeting the inclusion criteria

Date of first enrolment
01/06/2012

Date of final enrolment
31/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX3 7LF

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Joint Research Office
Block 60
Churchill Hospital
Old Road
Oxford
England
United Kingdom
OX3 7LE

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

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	01/03/2015		Yes	No
HRA research summary			28/06/2023	No	No