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The Pregnancy Physiology Pattern Prediction Study (4P Study)

Submission date
01/09/2014

Recruitment status
No longer recruiting

Registration date
29/12/2014

Overall study status
Completed

Last Edited
11/01/2021

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The two most recent Confidential Enquiries into Maternal Deaths reports in the UK have highlighted an urgent need to develop a national Modified Obstetric Early Warning System (known as MEOWS) to make sure that women who are developing life threatening complications of pregnancy are identified quickly, and referred and treated accordingly. Modified Early Obstetric Warning Charts (MEOWS) assign increasing scores (or colours) to each individual physiological measurement (blood pressure, heart rate, temperature, breathing rate and amount of oxygen in the blood) as they become more abnormal. If either the sum of scores for several physiological measurements, or a score for a single physiological measurement exceed set thresholds, an alert is triggered. We want to develop a database of physiology of pregnancy and the postpartum period (period from just after birth to around 6 weeks after birth) from which an evidence-based, robust early warning score can be developed.

Who can participate?
Pregnant women aged at least 16 without any underlying medical condition known to affect vital signs, that is blood pressure, heart rate, temperature, oxygen saturation levels (amount of oxygen in the blood) and respiratory (breathing) rate.

What does the study involve?
Participants have their vital signs measured by a research midwife at selected points throughout their pregnancy. After pregnancy they are required to carry out home monitoring of their own vital signs using a set of home monitoring equipment for approximately 2 weeks. Each participant is likely to be involved in the study from around 14 weeks of pregnancy to around 14 days postnatal (maximum 30 weeks to allow for women who deliver at 42 weeks). Vital signs data are collected from patients on a monthly basis from their recruitment to the study (at the first routine antenatal appointment or the nuchal scan) to two weeks postpartum. This is a combination of data recorded at regular antenatal visits, any in-hospital stay during pregnancy, delivery and immediately after birth, and data recorded by home monitors in the two weeks immediately after birth. Resting observations for the standard physiological variables used in the current MEOWS charts are recorded from each mother. Demographic, laboratory and medication data which may be related to vital signs is also collected. As a result, a large database of maternal and postpartum physiology will be assembled, from which an evidence-based,

national MEOWS will be developed for all stages of pregnancy, the intrapartum (during childbirth) and postpartum periods. A pregnancy stage specific alerting system will be created for use in monitored areas and hospital environments.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The 4P study has been set up by the University of Oxford and runs from The Oxford University Hospitals NHS Trust. Guys and St. Thomas Hospital London and The Newcastle Upon Tyne Hospitals NHS Foundation Trust are in the process of being set up as recruiting sites.

When is the study starting and how long is it expected to run for?
November 2014 to August 2017

Who is funding the study?
Biomedical Research Centre (BRC) (UK)

Who is the main contact?
Dr Peter Watkinson
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Study website
http://www.osprea.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Peter Watkinson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0 - 26 June 2014

Study information

Scientific Title
The Pregnancy Physiology Pattern Prediction Study (4P Study): an observational cohort study

Acronym
4P

Study objectives
The two most recent Confidential Enquiries into Maternal Deaths in the UK have highlighted an urgent need to develop a national Modified Obstetric Early Warning System (known as MEOWS) to aid the more timely recognition, treatment and referral of women who are developing life-threatening complications of pregnancy. The problem is complicated by the normal changes in maternal physiology that occur both during pregnancy and immediately after delivery. Very limited information exists from which to develop an evidence-based early warning system that is adapted to alert appropriately for the stage of pregnancy or postpartum period.
Although several local Modified Obstetric Early Warning Systems have been developed an evidence-based approach to identifying when women have become physiologically abnormal for their stage of pregnancy is required, to achieve widespread acceptance of a national MEOWS chart.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South East Coast - Brighton & Sussex, 13/08/2014, ref: 14/LO/1312

Study design
Two year multi-centre prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
http://www.osprea.ox.ac.uk/wp-content/uploads/2014/05/4p-PIS.docx

Health condition(s) or problem(s) studied
Vital signs during pregnancy, intrapartum and two weeks post partum

Interventions
Vital signs, including oxygen saturation levels, blood pressure, heart rate, respiration rate and temperature will be recorded onto a tablet and smartphone throughout pregnancy at 4-6 week intervals and daily for two weeks in the immediate postpartum period. The recordings are uploaded to a database under the participant's unique study number.

Intervention Type
Other

Primary outcome measure
To create a comprehensive database of physiological values during pregnancy, the intrapartum and postpartum periods for 1000 participants.

Secondary outcome measures
1. To develop a centile-based early warning score for pregnancy and the postpartum period.
2. To investigate new patterns within vital signs data in pregnancy

Overall study start date
01/11/2014

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. Over 16 years of age (parental consent to be obtained for participants <18 years old)
2. Pregnant with an intent to deliver in hospital
3. Able to understand written or spoken English or has their own interpreter willing to translate
4. Willing and able to use the home monitoring equipment
5. Within category 1 of the American Society of Anaesthesiologists' classification of physical status at enrolment (normal healthy patient without any clinically important comorbidity and without a clinically significant past/present medical history).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants

1000

Total final enrolment
1041

Key exclusion criteria
Any known medical condition expected by the recruiting clinician to alter maternal vital signs

Date of first enrolment
01/11/2014

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Nuffield Department of Clinical Neurosciences
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
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Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
Biomedical Research Council (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	01/09/2017		Yes	No
Results article	results	01/03/2020	07/02/2020	Yes	No
Results article	results	01/02/2021	11/01/2021	Yes	No
HRA research summary			28/06/2023	No	No