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Organisation of Early Pregnancy Units and its effects on quality of care

Submission date
28/06/2016

Recruitment status
No longer recruiting

Registration date
05/07/2016

Overall study status
Completed

Last Edited
26/01/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many women experience pain or bleeding in early pregnancy. This is quite worrying as it may mean that the pregnancy could miscarry. Most hospitals in this country have specialist departments to look after women presenting with early pregnancy problems. They are called Early Pregnancy Units. Although there are more than 200 Early Pregnancy Units around the country attended by tens of thousands women each year, we do not know what the best way is to set them up and how to run them to respond best to women's needs. The aim of this study is to analyse how Early Pregnancy Units operate, see how good they are at finding out whether the pregnancy is healthy or not, and how well women are treated and supported. We will also ask women to tell us about their experience of attending Early Pregnancy Units and tell us how this could be improved. We will also speak to members of staff working in the Units and ask for their opinions and suggestions. All of this information should help us to advise hospitals and the government on how to improve care for women with early pregnancy problems in the future.

Who can participate?
Pregnant women (16 years of age and over) attending Early Pregnancy Units because of early pregnancy complications

What does the study involve?
Women who agree to help us with the study are asked to complete a short health questionnaire during the clinic visit. Most women are also asked to complete a short questionnaire at least two weeks after their final visit to the unit. Some women are asked to complete a further questionnaire three months after being seen in the unit and a small number of women are asked to take part in an interview.

What are the possible benefits and risks of participating?
Women who agree to help with the study will receive the same care as usual which will not be affected in any way by taking part. There are no risks or direct benefits to women by participating in the study. However, the results of the study should help improve women's experience of early pregnancy care in the future.

Where is the study run from?
University College Hospital London (UK)

When is the study starting and how long is it expected to run for?
November 2015 to January 2019 (as of 19/10/2018)

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

Who is the main contact?
Davor Jurkovic

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.1

Study information

Scientific Title
Variations in the organisation of Early Pregnancy Assessment Units (EPAUs) in the UK and their effects on clinical, service and patient-centred outcomes

Acronym
VESPA

Study objectives
A recent NICE guideline on “Ectopic pregnancy and miscarriage” (CG154)1 published in December 2012 emphasises the need for good quality research to establish the effectiveness of Early Pregnancy Assessment Units (EPAUs). EPAUs are dedicated units within NHS hospitals that provide specialist care to women in the first three months of pregnancy. Women who experience pain or bleeding in the first weeks of pregnancy or women with a previous miscarriage or ectopic pregnancy are routinely seen in EPAUs. While most NHS hospitals in the UK have an EPAU, there are considerable variations between EPAUs in the levels of care they provide and their accessibility to women. In addition, staffing levels vary considerably between the units. The most cost-effective organisational model for an EPAU is unknown.
Early pregnancy problems are very common with 20% of recognised pregnancies ending in miscarriage and 2% of pregnancies being complicated by an ectopic pregnancy. Given the variation amongst units, women are likely to have different experiences of the services and the care provided.
We recently completed a pilot study of seven EPAUs across London to compare several clinical and service outcomes in units with different organisational structures, staffing levels and ease of access.
The study showed differences in several important clinical outcomes between different units. We used these findings to plan a larger study which is described in this protocol.

Hypothesis: The rate of hospital admissions is lower in EPAUs with high consultant presence than in units with low consultant presence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester Central Research Ethics Committee, 26/09/2016, ref: 16/NW /0587, IRAS 179311

Study design
Multi-methods approach including:
1. Prospective observational cohort study
2. Health economic evaluation including skill-mix and cost-utility model development
3. Patient satisfaction survey
4. Staff survey
5. Qualitative interviews with service users
6. Prospective hospital emergency care audit

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Early pregnancy

Interventions
We propose to collect information about all women who present to a sample of EPAUs, with suspected complications of early pregnancy, for initial or follow-up visits.

The main outcome of interest is the number of women who require emergency admission and stay in hospital. This could be either because a diagnosis cannot be made with certainty in the EPAU clinic, or because of the need for further treatment.
In addition to the primary outcome we will:
1. Examine the number of follow-up visits and ultrasound scans that are required to reach a diagnosis
2. Look at the number of surgical keyhole procedures that were performed for suspected ectopic pregnancy and the number of procedures which did not confirm this diagnosis
3. Record all women who had a burst ectopic pregnancy and required a blood transfusion
4. Collect and analyse information about women's experiences of the care they received in an EPAU and their satisfaction with it
5. Conduct workforce modelling of the most effective EPAU staffing configuration(s), based on the primary outcome
6. Conduct a cost-effectiveness analysis of alternative workforce models

We have estimated that we need to include 44 EPAUs nationwide. We based our calculations on our findings from the smaller study, which showed that quality of care appears to be better in the units where senior doctors (consultants) tend to spend more time working with other staff members who are looking after pregnant women. We will ensure that the units included in the study represent a good mixture of units located within both different types of hospitals and different geographic areas within the UK. The study will last for 2 years, allowing 6 months for set-up, 12 months for data collection, and 6 months for analysis.

The research team includes clinicians, academics, and lay members, and the conduct of the study will be overseen by a Study Advisory Group. The information obtained from this study will help to better organise EPAUs nationwide in order to ensure optimal clinical outcomes in the most cost effective way.

Intervention Type
Other

Primary outcome measure
Emergency hospital admissions as a proportion of women attending Early Pregnancy Units

Secondary outcome measures
1. Ratio of new to follow-up visits
2. Proportion of non-diagnostic ultrasound scans (pregnancy of unknown location)
3. Total number of emergency admissions of women presenting with early pregnancy complications
4. Proportion of laparoscopies negative for ectopic pregnancy

5. Ruptured ectopic pregnancies requiring blood transfusion
6. Estimated blood loss at operation
7. Patient satisfaction with the quality of care received
8. Staff experience of providing care
9. Proportion of women diagnosed with miscarriage treated surgically/medically/expectantly
10. Proportion of women diagnosed with ectopic pregnancy treated surgically/medically /expectantly
11. Visits to A&E departments
12. Admissions to ITU
13. Duration of admissions
14. Waiting times from referral to assessment
15. Quality of Life measures before and after assessment of women at the EPAU during initial and follow-up visits
16. Anxiety measured on a horizontal 10cm visual analog scale
17. Cost-effectiveness of different staffing models

Overall study start date
01/11/2015

Completion date
15/01/2019

Eligibility

Key inclusion criteria
Prospective observational cohort study (primary):
Pregnant women (16 years of age and over) attending Early Pregnancy Assessment Units because of suspected early pregnancy complications.

Health economic evaluation, patient satisfaction survey and qualitative interviews with service users:
Pregnant women (16 years of age and over) attending Early Pregnancy Assessment Units because of suspected early pregnancy complications who agree to sign a written consent to participate.

Hospital emergency care audit:
All women attending hospital emergency service because of early pregnancy complications over a period of three months.

Staff survey:
All members of staff directly involved in providing early pregnancy care.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
6600

Total final enrolment
6606

Key exclusion criteria
Health economic evaluation, patient satisfaction survey and qualitative study:
Women who are haemodynamically unstable, in severe pain and those who refuse consent to participate in the study.

Date of first enrolment
01/09/2016

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College Hospital London
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
30/10/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	26/01/2021	Yes	No

HRA research summary	28/06/2023	No	No