

Probability of viability estimation and anxiety levels in women with small seemingly empty gestational sacs

Submission date 15/01/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/01/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 23/05/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The study aims to find out if patients experience less anxiety when we do a test to calculate the chance of an ongoing pregnancy.

Who can participate?

Women who have had a scan that have shown a pregnancy sac in the womb but no embryo will be invited to take part. This scan finding means that it may be too early to see an embryo or else that it are a failing pregnancy and that the pregnancy will miscarry. It is very difficult for doctors to counsel women as we do not yet know what will happen to the pregnancy. Women will have different levels of anxiety until they know if the pregnancy is growing normally at the next scan.

What does the study involve?

Women that agree to take part in the study will be asked to complete an anxiety questionnaire. Following this they will be placed in one of two groups. Each patient is put into a group by chance (random). Group one will have a blood test and receive the probability of viability score and group 2 will not. Group 1 will need to have a sample of blood taken to test the level of the hormone progesterone. Patients will then be asked the best way to contact them and they will be given a follow up appointment for another scan, usually in about 2 weeks time. When the blood test result is available a calculation will be performed that will give us the chance that the pregnancy will continue as normal. The test results can be given either face to face or over the telephone. 7 days after your first appointment both groups will be contacted usually by telephone and the anxiety questions will be repeated. The follow up scan will then take place as usual. Women in group 2 will not receive this score. They will be asked to complete the anxiety questions after the first scan and then at 7 days. They will then be given a follow up appointment usually in about 2 weeks for another scan.

What are the possible benefits and risks of participating?

There may not get any individual benefit. We do not yet know whether the test will have any effect on anxiety levels. If the test lowers anxiety, then it could be used more widely in the future to help improve care for women in the same situation when they have had a scan and we

do not know whether the pregnancy is likely to continue. Taking the blood sample may be a little painful and may result in short-term bruising.

Where is the study run from?

The study will be run from the early pregnancy unit at Kings College Hospital and is sponsored by Kings College Hospital Foundation NHS Trust who is sponsoring the research.

When is the study starting and how long will it run for?

The study started in January 2012 and will run until have seen the number of patients needed to complete the study. We think this will be about 6 months.

Who is funding the study?

Kings College Hospitals NHS Foundation Trust (UK)

Who is the main contact?

Miss Jackie Ross

jackie.ross1@nhs.net

Contact information

Type(s)

Scientific

Contact name

Miss Jackie Ross

Contact details

Kings College Hospital NHS Foundation Trust

Kings College Hospital

Denmark Hill

London

United Kingdom

SE5 9RS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 5

Study information

Scientific Title

A prospective randomised interventional study of a test to predict viability in early pregnancy: psychological effect and patient acceptability

Study objectives

Women who are given the probability of a viable pregnancy will experience reduced anxiety levels while waiting for their repeat scan.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES committee London-Riverside, 08/12/2011, REC ref: 11/LO/1764

Study design

Prospective randomised controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Early pregnancy

Interventions

Patients will be randomised in to one of 2 groups.

Group 1 will be randomised to having probability of viability score and group 2 no score. Group 1 will have bloods taken for progesterone.

Contact details will be taken for both groups. A rescan will be arranged as per the usual plan.

The progesterone levels will be available later in the day and a probability of viability can be calculated using the following calculation:

probability of viability = $1/(1 + e^{-z})$, where $z = (6.091 \times \ln \text{progesterone}) - (0.159 \times \text{mean GSD}) - (0.164 \times \text{maternal age}) - 17.435$.

Patients in group 1 will then be informed of their score and the significance of this by telephone or face to face.

Both groups of patients will be contacted 7 days after their initial scan and a repeat Hospital Anxiety and Depression Scale (HADS) performed by telephone. Both groups will receive their follow up scan as per the usual protocol.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Difference in HADS at 7 days between cases and controls.

Secondary outcome measures

Prior to the re-scan 14 days from the initial scan group 1 will be asked two questions in order to establish if the patient found the test helpful.

1. Was it useful to receive the test result?
2. Would they choose to have the test again if they were in a similar position?

Overall study start date

01/01/2012

Completion date

01/06/2012

Eligibility**Key inclusion criteria**

1. Women (16-40 years) with a positive urine pregnancy test (Clearview HCG II)
2. Who have conceived spontaneously and have a single intrauterine gestational sac of <20mm mean gestational sac diameter (GSD) with no visible embryo on their first ultrasound scan. A yolk sac is not considered to be a visible embryo so these women will be included.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

A sample size of 69 in each group, Allowing for a 20% dropout and a 50% consent acceptance rate, a total number of 346 patients is required.

Key exclusion criteria

1. Assisted conception
2. Multiple pregnancy

3. Use of exogenous progesterone
4. Women who decline to participate
5. Women who intend to terminate the pregnancy
6. Women receiving treatment or investigation for psychiatric disorder
7. Non-English speaking [Hospital Anxiety and Depression Scale (HADS) not validated in other languages]

Date of first enrolment

01/01/2012

Date of final enrolment

01/06/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Kings College Hospital NHS Foundation Trust

London

United Kingdom

SE5 9RS

Sponsor information

Organisation

King's College Hospital NHS Foundation Trust (UK)

Sponsor details

c/o Zoe Harris

R&D Department

First Floor

Jennie Lee House

34 Love Walk

Denmark Hill

London

England

United Kingdom

SE5 5AD

Sponsor type

Hospital/treatment centre

Website

<http://www.kch.nhs.uk>

ROR

<https://ror.org/01n0k5m85>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Kings College Hospitals NHS Foundation Trust (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?
Results article	results	01/07/2014		Yes	No