ISRCTN76836892 https://doi.org/10.1186/ISRCTN76836892

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

Registration date
25/01/2013

Overall study status
Completed

Last Edited
23/05/2016

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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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

Protocol serial number
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

Study type(s)
Quality of life

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 × ln progesterone) – (0.159 × mean GSD)–(0.164 × 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(s)
Difference in HADS at 7 days between cases and controls.

Key secondary outcome(s))

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?

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

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)

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Kings College Hospitals NHS Foundation Trust (UK)

Results and Publications

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