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Can a test of preterm labour (quantitative fetal fibronectin) help diagnosis and clinical decision making?

Submission date
15/10/2015

Recruitment status
No longer recruiting

Registration date
27/10/2015

Overall study status
Completed

Last Edited
10/09/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
About 11% of all babies born worldwide are preterm (premature) meaning that they are born more than three weeks before their due date. Accurately predicting whether a woman will have a preterm delivery is notoriously challenging. Up to 80% of women who show signs of preterm labour remain pregnant after 7 days. Despite this, many women are given treatments aimed at preventing complications for their babies, should they be premature. This can be very costly and little is known about the effects for mothers and their babies if a preterm delivery does not take place. Fetal fibronectin (fFN) is a “glue-like” protein which attaches the amniotic sac (the fluid sac that contains and protects a fetus) to the lining of the womb. At the end of pregnancy, fFN begins to break down and can be detected in vaginal fluid. By measuring the concentration of fFN, it is possible to predict whether the baby is likely to arrive prematurely (quantitative foetal Fibronectin test). Generally, the result will either be positive (showing the fFN is present and so there is an increased chance of labour) or negative (where it is not present, ruling out the chance of labour). The aim of this study is to find out how accurate the quantitative foetal Fibronectin (qfFN) test is at predicting preterm delivery. The results are compared with two pre-term birth marker tests currently available in the NHS (Actim Partus and Partosure).

Who can participate?
Women who are showing signs of going into labour prematurely.

What does the study involve?
Women have a vaginal swab taken so that levels of quantitative fetal fibronectin can be measured. This will allow the researchers to predict the chance of the women delivering their babies prematurely over the next seven days. Two additional vaginal swabs are also taken for the Actim Partus and Partosure tests. Regular contact is kept with the women in the form of telephone interviews so that the number of women who have had a preterm delivery can be measured.

What are the possible benefits and risks of participating?
There are no direct benefits to women or their babies for participating in this study, although

some women gain satisfaction from contributing research studies which will improve future care for women with preterm labour. There are very few risks from participation as qfFN is the most commonly used test for preterm labour, and it is considered to be safe. Knowledge of qfFN results may increase or decrease anxiety levels, and this will be assessed as part of the trial.

Where is the study run from?
Royal Infirmary of Edinburgh (lead centre) and three Scottish, four Welsh and 19 English hospitals (UK)

When is the study starting and how long is it expected to run for?
December 2015 to January 2019 (as of 04/10/2018)

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
1. Ms Lisa Wotherspoon (public)
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
HTA 14/32/01

Study information

Scientific Title
QUIDS – Quantitative Fibronectin to help Decision-making in women with Symptoms of Preterm Labour

Acronym
QUIDS

Study objectives
In women with symptoms suggestive of preterm labour, quantitative fetal fibronectin will help rule out preterm labour and aid decision making.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. QUIDS – West of Scotland REC 5, 22/03/2016, ref: 16/WS/0068
2. QUIDS 2 – West of Scotland REC 5, 10/05/2017, ref: 17/WS/0081

Study design
Multi-centre prospective cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Preterm labour

Interventions
Women with symptoms of preterm labour (22-34 weeks gestational age) who are participating in the study will have a vaginal swab sample taken to test levels of quantitative fetal fibronectin in order to predict the likelihood of preterm delivery within the next 7 days. Women will be followed up until delivery to determine the diagnostic accuracy of the test.

Added 15/03/2017:
QUIDS 2 sub study:
The sub study will involve taking two additional cervical swabs from the participants to be used for testing additional pre-term birth marker tests currently available in the NHS (Actim Partus and Partosure). These results will be compared to the results and the model developed in QUIDS.

Intervention Type
Other

Primary outcome(s)
Delivery rate is measured within 7 days of enrollment in the study

Key secondary outcome(s))
1. Acceptability of the qfFN, measured by telephone interviews in a subset of participants (n=30) at 48 hours following test
2. Anxiety, measured using the State Trait Anxiety Index questionnaire pre and 48 hours post test
3. Cost effectiveness of fFN measured by decison analytical modelling until discharge from hospital
4. Delivery within 48 hours of enrollment in the study
5. Rate of spontaneous preterm delivery before 34 weeks
6. Rate of spontaneous preterm delivery before 37 weeks

Completion date
30/01/2019

Eligibility

Key inclusion criteria
1. Women with signs and symptoms of preterm labour 24-34 weeks (or earlier gestation if the fetus is considered potentially viable) in whom hospital admission, inter-hospital transfer or treatment (antenatal steroids, tocolysis or magnesium sulphate) is being considered
2. Signs and symptoms may include any or all of the following:
2.1. Back pain
2.2. Abdominal cramping
2.3. Abdominal pain
2.4. Light vaginal bleeding
2.5. Vaginal pressure
2.6. Uterine tightenings or contractions
2.7. Cervical effacement or dilatation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

Female

Total final enrolment
2924

Key exclusion criteria
1. Women who have moderate or severe vaginal bleeding
2. Women who have cervical dilatation greater or equal to 3cm
3. Women with confirmed rupture of membranes
4. Sexual intercourse, vaginal examination or transvaginal ultrasound in the preceding 24 hours factors can invalidate results and so these women will be initially excluded from the study. They can later be included if still symptomatic after 24 hours, when fFN accuracy will be restored

Date of first enrolment
01/09/2016

Date of final enrolment
31/10/2018

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Simpson Centre for Reproductive Health, Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4TJ

Study participating centre
Birmingham Women's Hospital
Mindelsohn Way
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B15 2TG

Study participating centre
Nottingham University Hospitals
Derby Road

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NG7 2UH

Study participating centre
West Middlesex University Hospital
Twickenham Road
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Sponsor information

Organisation
University of Edinburgh and NHS Lothian ACCORD

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Qualitative results	01/10/2019	12/08/2019	Yes	No
Protocol article	protocol	19/04/2018		Yes	No
Funder report results		01/09/2021	10/09/2021	No	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
Other publications	Development and validation of a risk prediction model	06/07/2021	30/07/2021	Yes	No
Protocol file	version v7.0	16/08/2018	11/01/2019	No	No
Protocol file	version v5.0	23/10/2018	11/01/2019	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes