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Prediction of adverse pregnancy outcomes following induction of labour

Submission date
26/01/2016

Recruitment status
No longer recruiting

Registration date
02/02/2016

Overall study status
Completed

Last Edited
16/05/2016

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Although most labours begin naturally, however around one third of women need help to get started. In these cases, a healthcare professional will often “induce” labour. Although the aim of induction is to achieve a vaginal delivery, it is not always successful and some women end up having a caesarean section (an operation where the child is delivered through a cut in the abdomen). Currently, there are no effective methods to predict which women will not respond favourably to induction of labor or how long this process is likely to take. The aim of this study is to develop techniques to help predict whether induction will result in vaginal delivery or caesarean section.

Who can participate?
Women aged 18 or over with a single baby pregnancy, who have been scheduled for an induction of labour at Medway Maritime Hospital.

What does the study involve?
All women at Medway Maritime Hospital receive a routine clinical assessment in the pre-induction clinic, which involves an ultrasound scan of the baby, digital vaginal examination and a blood test. Participants are also offered an ultrasound scan to measure the length and dilation of the neck of the womb (cervix) and to find out how low the baby’s head is in the pelvis. For those agreeing to take part in the study, a swab of the vagina and another blood sample is taken to be tested in the laboratory for natural indicators (biochemical markers) as well as receiving an ultrasound scan which can help to predict the result of the induction. The amount of women who go into labour following induction are then recorded and compared to the results of prediction from the biochemical markers and ultrasound scan to find out how well the tests are able to predict the results of the induction.

What are the possible benefits and risks of participating?
There are no direct benefits or risks for participants taking part in this study.

Where is the study run from?
Medway Maritime Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2015 to June 2017

Who is funding the study?
Fetal Medicine Foundation (UK)

Who is the main contact?
1. Dr Alexander Frick (public)
2. Mr Ranjit Akolekar (scientific)

Contact information

Type(s)
Public

Contact name
Dr Alexander Frick

ORCID ID
http://orcid.org/0000-0001-8013-3679

Contact details
Fetal Medicine Research Institute
16-20 Windsor walk
London
United Kingdom
SE5 8BB

Type(s)
Scientific

Contact name
Prof Ranjit Akolekar

Contact details
Medway Maritime Hospital
Fetal Medicine Unit
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.0

Study information

Scientific Title
Prediction Of adverse Pregnancy outcomes following INduction of labour in singleton pregnancies: A single centre observational study

Acronym
POPIN

Study objectives
The aim of this study is to assess if a combination of ultrasound findings and biochemical markers from vaginal secretions and maternal blood can better predict vaginal delivery than traditional methods such as the Bishop Score.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Dulwich Research Ethics Committee, 31/03/2016, ref: 16/LO/0367

Study design
Single-centre prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

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
Pregnancy and childbirth

Interventions
Women attending a pre-induction clinic who are participating in the study will have a vaginal swab taken to test levels of quantitative fetal fibronectin and placental alpha-macroglobulin-1 prior to induction of labour. They will also have a transperineal ultrasound (TPUS) to measure the angle of progression, head-perineum distance and sonographic assessment of cervical

dilatation. The results from these assessments will be combined with maternal characteristics to predict mode of delivery.

Patients will then be followed throughout the induction and labour process, with the transperineal ultrasound assessments repeated on a 4 hourly basis to compare the effectiveness of ultrasound with clinical vaginal examination.

Women will be followed until delivery to determine the accuracy of the pre-induction test and intrapartum ultrasound assessments. The total duration of observation will vary from depending on the length of induction and labour, but will typically be 1-3 days. There will be no need for follow up after delivery.

Intervention Type
Other

Primary outcome measure
Detection rate and false positive rate for predicting vaginal delivery following induction of labour is measured using a combination of maternal characteristics, ultrasound findings, and biochemical markers from a pre-induction clinic at the time of delivery.

Secondary outcome measures
1. Detection rate for caesarean section for failure to progress is measured using a combination of maternal characteristics, ultrasound findings, and biochemical markers from a pre-induction clinic at the time of delivery
2. Detection rate for caesarean section for fetal distress is measured using a combination of maternal characteristics, ultrasound findings, and biochemical markers from a pre-induction clinic at the time of delivery
3. Detection rate for maternal haemorrhage greater than 1500 ml is measured using a combination of maternal characteristics, ultrasound findings, and biochemical markers from a pre-induction clinic at the time of delivery
4. Detection rate for neonatal intensive care admission is measured using a combination of maternal characteristics, ultrasound findings, and biochemical markers from a pre-induction clinic at the time of delivery
5. Effectiveness of intrapartum ultrasound in predicting vaginal delivery as compared to traditional vaginal examination is determined at the time of delivery

Overall study start date
01/11/2015

Completion date
01/10/2017

Eligibility

Key inclusion criteria
1. Female
2. Viable singleton pregnancy
3. Aged 18 years or over
4. Cephalic presentation
5. Attending pre-induction of labour clinic
6. Informed written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
1000

Key exclusion criteria
1. Multiple pregnancies
2. Women with fetal demise
3. Women less than 18 years
4. Women who are unconscious or severely ill, those with learning difficulties, and serious mental illness
5. Malpresentation

Date of first enrolment
01/03/2016

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medway Maritime Hospital
Medway NHS Foundation Trust
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Sponsor information

Organisation
Medway NHS Foundation Trust

Sponsor details
Windmill Road
Gillingham
England
United Kingdom
ME7 5NY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01apxt611

Funder(s)

Funder type
Charity

Funder Name
Fetal Medicine Foundation

Alternative Name(s)
FMF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in leading peer reviewed scientific journals for obstetric ultrasound, such is Ultrasound in Obstetrics & Gynecology.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No