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Comparison on patient satisfaction with Cervical Ripening Balloon using inpatient and outpatient protocol

Submission date
24/04/2018

Recruitment status
Stopped

Registration date
29/05/2018

Overall study status
Stopped

Last Edited
10/08/2020

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Induction of labour is one of the most common procedures in obstetrics and about 1 in 4 women will go through the process. Generally, induction of labour methods can be divided into: mechanical (intracervical catheter, laminaria, synthetic osmotic cervical dilators, extra-amniotic saline infusion) and pharmacological (the use of drugs, like prostaglandins and oxytocin).
The aim of this study is to assess patients' overall satisfaction with Cook Cervical Ripening Balloon using two different protocols (outpatient and inpatient) and to determine the difference between them, if any, by using a questionnaire.

Who can participate?
Pregnant women aged 18 to 40 years who have never given birth before

What does the study involve?
Patients are divided into two groups. Both groups receive Cook Cervical Ripening Balloon for the induction of labour. They are exposed to the product for the same period of time (12 hours). The only difference between two groups is where patients are during the period of induction (those in the inpatient group remain in the hospital whilst those in the outpatient group go home).

What are the possible benefits and risks of participating?
Participants may benefit from induction of labour, as Cook Cervical Ripening Balloon is an effective and proven tool. Risks in the induction of labour are well known but so far, publications have shown CRB has reduced risk compared with prostagladins (most usual method for induction of labour) as stated in the official leaflet of CRB.

Where is the study run from?
National Maternity Hospital (Ireland)

When is the study starting and how long is it expected to run for?
September 2017 to January 2020

Who is funding the study?
National Maternity Hospital (Ireland)

Who is the main contact?
Dr Branko Denona (Public)

Contact information

Type(s)
Public

Contact name
Dr Branko Denona

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Contact details
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Dublin
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Pilot comparative study on patient satisfaction with Cervical Ripening Balloon using inpatient and outpatient protocol

Study objectives
To assess patients’ satisfaction on induction of labour with Cook’s Cervical Ripening Balloon using two different protocols, inpatient and outpatient. Satisfaction of each protocol is assessed by patients' completed questionnaire.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Maternity Hospital Dublin Ethics Committee, 29/03/2018, ref: EC 04.2018

Study design
Prospective comparative pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Obstetrics: induction of labour

Interventions
40 patients who fulfill criteria and are willing to participate in the study are equally divided into two different groups. In both groups Cook Cervical Ripening Balloon (CRB) is inserted in the cervix of the uterus and is removed after 12 hours as per instructions of the manufacturer. CRB can be removed before expiration of 12 hours if there is a clinical indication.
Patients in the first group (inpatient protocol) remain in the hospital after CRB is placed. Other group of patients (outpatient protocol) leave the hospital after placement of the CRB and return when the CRB is due to be removed. CRB is used for the same period of time in both groups. After removal of the CRB, patients in both groups are examined and continue induction of labour as per hospital protocol.

Intervention Type
Device

Primary outcome measure
Patient satisfaction with Cook Cervical Ripening Balloon is measured using Patient Experience Questionnaire post induction process

Secondary outcome measures
1. Efficiency of Cook’s CRB for induction of labour is assessed by possibility to perform artificial rupture of membranes post removal of CRB
2. Delivery within 24 hours of receiving induction of labor method is recorded.
3. Cesarean delivery rate is recorded at delivery.
4. Instrumental delivery rate is recorded at delivery.
5. Additional use of prostaglandin (1 or 2 doses) is recorded after reassessment following removal of CRB
6. Additional use of oxytocin for labour induction or augmentation is recorded after reassessment following removal of CRB

7. Maternal infection defined as maternal temperature greater than 38ºC, endometritis, chorioamnionitis or antibiotic usage is recorded following placement of CRB
8. Neonatal adverse events (if any) are recorded throughout.

Overall study start date
01/09/2017

Completion date
31/01/2020

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Nulliparous women with singleton pregnancies
2. Aged 18 to 40 years
3. The fetus is in cephalic presentation
4. Low risk pregnancies going for induction of labour for postdates pregnancies as per protocol in National Maternity Hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
40

Key exclusion criteria
1. Any pre-existing medical condition or medical condition of pregnancy
2. Pathological CTG prior to induction
3. Oligohydramnios or any other abnormal findings on post-dates scan
4. Maternal age <18 years old or >40 years old

Date of first enrolment
01/05/2018

Date of final enrolment
01/07/2020

Locations

Countries of recruitment
Ireland

Study participating centre
National Maternity Hospital
Holles Street
Dublin
Ireland
D2

Sponsor information

Organisation
National Maternity Hospital

Sponsor details
Holles Street
Dublin
Ireland
D2

Sponsor type
Hospital/treatment centre

Website
http://www.nmh.ie/

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Maternity Hospital

Results and Publications

Publication and dissemination plan
The study is planned to be published in peer reviewed journal.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
Data will not be available as the this is only a pilot study and would most likely be followed by a larger, cohort study. For this reason collected data will only be saved for the time of the study and once completed will be erased and hold no value for the future studies except for the final results which will be published.

IPD sharing plan summary
Not expected to be made available