ISRCTN50041378 https://doi.org/10.1186/ISRCTN50041378

A feasibility study and pilot randomised trial of an intervention designed to reduce unnecessary caesarean section in Ireland

Submission date
12/02/2018

Recruitment status
Stopped

Registration date
25/02/2018

Overall study status
Stopped

Last Edited
15/05/2019

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
Concern has been expressed globally at the rising caesarean section (CS) rate, and this has not resulted in a decrease in health problems for mothers and babies, indicating that many CSs are not necessary. Death and severe health problems are increased (3-fold) for women following CS compared with vaginal birth, and more newborn babies require oxygen after CS. This study aims to develop and test a package of care that is designed to reduce overall CS rates in Ireland, safely.

Who can participate?
Pregnant women aged over 18 years

What does the study involve?
Participants giving birth at one site receive the intervention, and those at the other site receive standard care. All participants complete three health and wellbeing surveys, one in pregnancy, one at 3 months after their baby is born and a final survey 6 months after their baby is born. Hospital records are accessed to gather information on their pregnancy, labour and birth (all information is kept strictly private and confidential). Participants in the intervention hospital also attend two antenatal classes where information specific to CS birth is presented and discussed.

What are the possible benefits and risks of participating?
The main benefit is that participants are helping to answer whether the information package is effective or not in reducing caesarean section rates overall. If their hospital has been allocated to test the new programme, it is possible that participants may find the information beneficial. There are no known risks to taking part in this study.

Where is the study run from?
1. The Coombe Women and Infants University Hospital (Ireland)
2. The Rotunda Hospital (Ireland)

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

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
Prof Cecily Begley (Public)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
DIFA-2017-011

Study information

Scientific Title
Reducing caesarean section rates in Ireland: a feasibility study and pilot randomised trial of an evidence-based intervention designed to reduce caesarean section safely

Acronym
REDUCE

Study objectives
A complex package of care, based on evidence, can reduce overall caesarean section rates

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Faculty of Health Sciences, Research Ethics Committee Trinity College Dublin, 19/12/2017, ref: 170501
2. Rotunda Hospital Research Ethics Committee Dublin, 15/12/2017, ref: REC-2017-026
3. The Coombe Women and Infants Hospital Research Ethics Committee Dublin, 10/10/2017, ref: 21-2017

Study design
Feasibility study and pilot cluster randomised trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Labour and delivery

Interventions
The study sites (n=2) are randomly allocated to the intervention or control by an independent statistician with no connection to the trial, using the R-software.
The intervention is developed, as part of the overall trial, using focus group interviews (FGIs) (4 with 3-6 women and their partners, 4 with 3-6 clinicians) in the hospital allocated randomly to the intervention arm. The FGIs ascertain views on, and barriers to, facilitating vaginal birth (FGIs will not be held in the control site so as to avoid contamination of the population in advance of the trial) and an overview of systematic reviews on antenatal and intrapartum interventions to identify those interventions that have shown to be effective for reducing CS. Based on existing evidence, the intervention will likely consist of an appointment of an obstetric and midwife opinion leader (OOL, MOL) who will facilitate women-centred, evidence-based antenatal classes (2 classes) and information session for clinicians, providing accurate information on the risks and benefits of both VBAC and repeat CS, second opinions for all CSs (other than category 1), peer-review of each CS and feedback, reducing induction of labour rates, support of clinicians and women to choose normal options over medical intervention (e.g. mobility instead of oxytocin, water-bath instead of pharmacological pain relief, reducing use of EFM in low-risk women). The protocol will be updated in Aug 2018 when the intervention is finalised.
Participants at the control site receive usual care as per current hospital practice.
Participants at both sites are followed through pregnancy, up to 6 months postpartum.

Intervention Type
Behavioural

Primary outcome(s)
Caesarean section rate (overall per site) is measured using hospital birth records

Key secondary outcome(s))
1. Labour interventions (e.g. induction and acceleration of labour, pain relief used, electronic fetal monitoring) are measured by reviewing women's hospital labour and birth records.
2. Maternal/neonatal morbidities (e.g. postpartum haemorrhage, perineal trauma, wound

infection, need for neonatal resuscitation, neonatal admission to intensive care, readmission to hospital) are assessed using hospital records.
3. Mother and baby health problems are assessed using self-completion surveys (health and wellbeing questionnaires that include the SF-36 instrument) during pregnancy and at 3 and 6 months post natal.
4. Clinician attitudes to caesarean section are measured by a self-completion questionnaire adapted from the UK National Sentinel Caesarean Section Audit.
5. Feasibility and pilot outcomes (% eligible and participating, time to recruit, etc.) are assessed using trial screening and eligibility forms, numbers participating (consent forms) and time to recruit full sample size (months).

Completion date
30/09/2020

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Pregnant woman
2. Aged over 18
3. Speak either English or a language for which translation is available
4. Give informed consent

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
Vaginal birth contraindicated at time of booking

Date of first enrolment
01/03/2018

Date of final enrolment
29/02/2020

Locations

Countries of recruitment
Ireland

Study participating centre
The Coombe Women and Infants University Hospital
Rialto
Dublin
Ireland
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Study participating centre
The Rotunda Hoapital
Parnell Strett
Dublin
Ireland
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Sponsor information

Organisation
Health Research Board

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Research organisation

Funder Name
Health Research Board (Ireland)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to a lack of ethical approval granting permission for this.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1	23/02/2018	01/04/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes