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Improving the organisation of maternal health service delivery, and optimising childbirth, by increasing vaginal birth after caesarean section (VBAC) through enhanced women-centred care

Submission date
17/03/2013

Recruitment status
No longer recruiting

Registration date
03/04/2013

Overall study status
Completed

Last Edited
10/03/2020

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

There is a wide variation across Europe in the proportion of pregnant women who have a caesarean section and concern that these proportions are increasing. For example, in the Netherlands only around 15 in every 100 births are by caesarean section but the figure is 38 per 100 in Italy. This is worrying because a woman who has a caesarean section, rather than a vaginal birth, is at a higher risk of suffering serious complications, such as needing a hysterectomy or blood transfusion, or dying. She is also five times more likely to develop an infection in the period after her baby is born. Much of the increase in caesarean sections in recent years is due to a cascade effect, in which a woman who has had one caesarean section is much more likely to have one again if she has another baby. In some places, it has become common practice for a woman who has had a caesarean section to have this procedure again as a matter of routine. The alternative, vaginal birth after caesarean (VBAC), has been widely recommended, results in fewer undesired results or complications, and is the preferred option for most women. However, VBAC rates in some countries are much lower than in other countries. For example, the rates are 45-55% in the Netherlands, Norway, and Sweden but only 29-36% in the three countries that will take part in this study: Germany, Ireland and Italy. This difference is equivalent to 160,000 unnecessary caesarean sections every year in Europe, at an extra direct annual cost of more than 150 million. This study called OptiBIRTH will test a specially developed approach to try to improve the VBAC rate. It will attempt to increase VBAC rates from 25% to 40% through increased women-centred care and womens involvement in their care.

Who can participate?

Women who have had one previous caesarean section, from the 16 hospitals in Germany, Ireland and Italy that have agreed to join the study. Each hospital will aim to recruit a minimum of 120 women.

What does the study involve?

Each of the 16 hospitals will be randomly allocated to be either an intervention site or a control

site. The allocation at random (called randomisation) will be done six to eight months in advance of recruiting pregnant women to the study, to allow sufficient time for the intervention to be put in place in the intervention hospitals. Hospitals that are allocated to the intervention group will deliver a new package of evidence-based education for women and their practitioners, introduce communities of practice (in which women and practitioners share knowledge), encourage opinion leaders and facilitate joint decision-making by women and practitioners, and conduct audit and peer review of caesarean sections. Hospitals that are allocated to the control group will continue with their usual practice, but will be offered the OptiBIRTH intervention at the end of the study. VABC and other outcomes that are related to maternity care of women will be measured before and during the study, to assess changes between the intervention and control hospitals.

What are the possible benefits and risks of participating?
There are no known risks to taking part in the OptiBIRTH study. Women in the intervention group may find the information they receive beneficial and some women may experience a reduction in interventions, a greater sense of empowerment in making decisions, and an increased sense of control over giving birth. However, the main benefit from taking part is that it will allow participants women to be part of the process of answering whether this standardised information package is effective or not in improving VBAC rates.

Where is the study run from?
16 hospitals in Germany, Ireland and Italy

When is the study starting and how long is it expected to run for?
Women will be recruited to the trial over 18 to 24 months from December 2013.

Who is funding the study?
The study is funded by the FP7 programme of the European Union.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomised trial of enhanced women-centred care, seeking to improve the organisation of maternal health service delivery and optimise childbirth, by increasing vaginal birth after caesarean section (VBAC)

Acronym
OptiBIRTH

Study objectives
Using a cluster randomised trial, the OptiBIRTH study will attempt to increase the proportion of women having a vaginal birth after a previous caesarean section. It was been powered to detect an increase in vaginal birth after caesarean section (VBAC) rates from 25% to 40%, through increased women-centred care and womens involvement in their care. The intervention involves evidence-based education of women and clinicians, introduction of communities of practice (women and clinicians sharing knowledge), opinion leaders, audit and peer review of caesarean sections in each site, and joint decision-making by women and clinicians. The clusters will be hospitals, with five or six hospitals in each of three countries (Germany, Ireland and Italy), and each hospital seeking to recruit 120 consecutive women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Faculty of Health Sciences Ethics Committee, Trinity College Dublin, Ireland, 27/06/2012

Study design
Multi-centre cluster randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnancy

Interventions
1. Evidence-based education of women and clinicians, introduction of communities of practice (women and clinicians sharing knowledge), opinion leaders, audit and peer review of caesarean sections in each hospital, and joint decision-making by women and clinicians. The content and

details of the intervention will be determined through systematic reviews and qualitative research.
2. Usual care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Change from baseline in each hospital in the proportion of women who have had one previous caesarean section who have a vaginal birth during the study

Key secondary outcome(s))
These secondary outcome measures will be collected using routine data where possible, will require the identification of reliable, robust and feasible measurement instruments, and might be collected on a sub-set of the participating women.

1. Gestational age at birth
2. Length of labour
3. Emotional well-being, feelings of anxiety, control, satisfaction with care and perception of involvement in care, during pregnancy and the postnatal period
4. Intrapartum interventions (induction or augmentation of labour, use of epidural and fetal monitoring, mode of birth)
5. Maternal morbidities during pregnancy and the postnatal period (for example, pain, postpartum haemorrhage, wound infection, abdominal pain, depression)
6. Neonatal morbidities (resuscitation, Apgar scores, admission to intensive care)
7. Breastfeeding
8. Length of hospital stay (mother and infant)
9. Readmission

Health economic analyses will be done using data on clinical outcomes, direct costs (such as length of stay and antibiotic use) and indirect costs (such as productivity loss) during pregnancy and postnatal period.

The study will also seek to assess adherence to guidelines and practice protocols, adherence to intervention quantity and quality, and midwife-centred variables; to compare and contrast findings across the different hospitals.

Completion date
30/05/2015

Eligibility

Key inclusion criteria
1. Pregnant women aged over 18 years
2. Who have had one previous caesarean section
3. Who speak a language for which translation is available
4. Who give their consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
2002

Key exclusion criteria
Women for whom a vaginal birth is contraindicated

Date of first enrolment
01/12/2013

Date of final enrolment
30/05/2015

Locations

Countries of recruitment
Germany

Ireland

Italy

Study participating centre
Trinity College Dublin
Dublin
Ireland
D2

Sponsor information

Organisation

Trinity College Dublin (Ireland)

ROR
https://ror.org/02tyrky19

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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	06/03/2020	10/03/2020	Yes	No
Protocol article	protocol	30/11/2015		Yes	No
Other publications	process evaluation	05/01/2018		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes