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Process for decision-making, obstetrical risk management and mode of delivery after a prior cesarean delivery in Québec

Submission date
01/08/2015

Recruitment status
No longer recruiting

Registration date
20/08/2015

Overall study status
Completed

Last Edited
15/12/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 14/03/2019:
Background and study aims
The number of cesarean sections (CS) continues to increase in industrialized countries. In Canada, for example, the percentage increased from 21.2% to 26.3% between 2000-2006. Over 30% of CS's are performed because the mother has had one for a previous pregnancy. Every year, over 30,000 women who have undergone a CS in the past will be faced with a difficult choice for their next pregnancy, that is, whether they should plan for a second CS or have a trial of labor (TOL) and try for a vaginal birth after cesarean (VBAC). One significant but rare risk of a VBAC is a uterine rupture (rupture of the womb). The uterine rupture is a obstetrical emergency and is the main complication associated with a TOL. However, although having a second cesarean delivery may help prevent uterine rupture in most cases, it carries with it a higher risk if both maternal and perinatal (just before and just after birth) complications. Repeat CS is now considered routine treatment for mothers who have had a CS in the past and health professionals hesitate, due to medical-legal risk, to recommend a TOL in the absence of a validated and effective method that can predict the chances of a successful VBAC and the risk of uterine rupture. The PRISMA program, includes a professional training program from the Society of Obstetricians and Gynaecologists of Canada to standardize intrapartum (childbirth) management for a TOL. It includes a decision aid tool to support women's decision making in the choice of the mode of delivery (DAT), an estimate of the risk of uterine rupture using ultrasound measurement of lower uterine segment (LUS) thickness (MSI) and an estimate of the chance of VBAC success. The aim of this study is to test whether the PRISMA program will reduce the rates of major complications during childbirth for mothers who have had a previous CS.

Who can participate?
Pregnant women who have had one prior CS at a participating center where the newborns were at least 22 weeks and weighed at least 500g at point of delivery.

What does the study involve?
Participants are grouped according to level of care and then randomly allocated into one of two groups, intervention or control. Participants in the intervention group are asked to fill-out a

decision aid tool about how they want their baby to be delivered. Their physician then estimates their chance of VBAC success during the pregnancy and at the time of the admission for delivery and estimates their risk of uterine rupture, using abdominal and transvaginal ultrasound measurement of LUS thickness between 35 and 38 weeks. The physician and the woman then decide together how the baby should be delivered. Participants in the control group receive usual care. Assessments include any adverse effects on the mother or child during or just after birth and the number of successful VBACs.

What are the possible benefits and risks of participating?
Women will have access to clinical tools that will facilitate the choice for a TOL or an elective repeat cesarean delivery. In addition, women will have a third-trimester ultrasound and will be informed of their risk of uterine rupture, in order to determine if they can attempt a safe vaginal delivery. There is no anticipated risk, abdominal and transvaginal ultrasounds are painless and present no risk for the woman or the baby.

Where is the study run from?
Hospital of Laval University (Canada)

When is the study starting and how long is it expected to run for?
Duration of the study: from September 2015 to December 2019
a) Recruitment of centers: from September 2015 to March 2016
b) Baseline period in all centers participating to the trial: from April 2016 to March 2017
c) Randomization and implementation of the PRISMA program in the intervention group: from April 2017 to August 2017
d) Intervention period: beginning in the intervention group from September 2017 to December 2017, depending on the starting date in each intervention center, for a duration of 2 years (from August 2019 to December 2019). In the control group, the data will be collected during the intervention period from September 2017 to August 2019. An additional period, excluded from the main analysis, will be collected from September 2019 to December 2019 in order to assess any potential temporal (time-related) bias associated to the different starting dates in the intervention group.

Who is funding the study?
Canadian Institutes of Health Research

Who is the main contact?
Professor Nils Chaillet, nils.chaillet@fmed.ulaval.ca

Previous plain English summary:
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Who is the main contact?
Professor Nils Chaillet

Contact information

Type(s)
Scientific

Contact name
Prof Nils Chaillet

Contact details
Mother-child center CHUL (Centre mère-enfant du CHUL)
CHU de Québec
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Additional identifiers

Protocol serial number
CIHR NRF-142448

Study information

Scientific Title
Process for decision-making, obstetrical RISk management and Mode of delivery After a prior cesarean delivery in Québec (PRISMA): a multicentre, two arms, randomized cluster trial

Acronym
PRISMA

Study objectives
1. Primary hypothesis
The PRISMA program will result in a reduction in the rate of major perinatal morbidity among the hospitals following the intervention compared to control hospitals. The trial will have the power to detect a relative reduction of 25% in the rate of major perinatal morbidity between groups
2. Secondary hypotheses
This program will result in:
2.1. A reduction in major maternal morbidity
2.2. A reduction in both minor maternal and minor perinatal morbidity
2.3. An augmentation in the Vaginal Birth After Cesarean rate

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Laval Regional Ethics Board, 09/12/2015, ref: MP-20-2016-2718

Study design
Multicentre stratified, cluster randomized, parallel-group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Choice of mode of delivery among women with one prior cesarean delivery

Interventions
1. Intervention group hospitals:
1.1. A tool to assess the woman a priori intentions for a trial of labor or an elective repeat cesarean delivery
1.2. An estimate of the risk of uterine rupture using ultrasound measurement of lower uterine segment thickness
1.3. An estimate of the chance of success of trial of labor using demographic and patient factors with a validated decision aid (Grobman nomogram)
1.4. A professional training program from the Society of Obstetricians and Gynaecologists of Canada to standardize management of women with one prior cesarean delivery and intrapartum management for a trial of labor
2. Control group hospitals:
2.1. Usual care

Intervention Type
Mixed

Primary outcome(s)
1. Major perinatal morbidity measured at the mid and at the end of the 2-years intervention period.
This composite outcome includes:
1.1. In utero, intrapartum and neonatal death, defined as the fetal death in utero, during labor or as the newborn death at less than 28 days of age (excluding lethal congenital abnormalities)
1.2. APGAR score at 5 mn < 4
1.3. Metabolic acidosis (umbilical arterial pH < 7 + base excess ≤ -12 mmol/l)
1.4. Major trauma (skull fracture, subdural / subarachnoid haemorrhage, brachial plexus injury, spinal-cord injury, major genital injury, paresis/paralysis at discharge)
1.5. Intracerebral / Intraventricular haemorrhage (grade 3 and 4)
1.6. Periventricular leukomalacia
1.7. Seizure (occurring from delivery to discharge)
1.8. Invasive mechanical ventilation with endotracheal intubation
1.9. Major respiratory morbidity (BPD : neonatal bronchopulmonary dysplasia treated with oxygen or ventilation at 36 weeks post-menstrual age or at 28 days of life, PPHN : Persistent Pulmonary Hypertension of the Newborn, Pneumothorax, Pulmonary haemorrhage, Hyaline membrane disease requiring mechanical ventilation)
1.10. Necrotising enterocolitis (NEC) - (stage 2 and 3)
1.11. Hypoxic-ischemic encephalopathy (APGAR 5mn < 4 + pH < 7 + base excess < -12 mmol/L + seizure)
1.12. Proven neonatal sepsis/infection (positive blood or cerebrospinal fluid culture)
1.13. Hypotension requiring vasopressor support
2. Data will be collected every day from women and neonatal clinical records during the 3.5 years of the program in the 40 hospitals (20 control and 20 interventions), to compare major perinatal morbidity in the intervention group with the rate in the control group at the end of the 2-years intervention period (year 3 and 4).
3. In the primary intention-to-treat analyses, we will assess the effect of the intervention on the rate of major perinatal morbidity using the multivariable generalized-estimating-equations extension of logistic regression, with an exchangeable covariance matrix, to account for the clustering of women within hospitals.

4. Changes in the risk of major perinatal morbidity in the two study groups between the 1-year baseline (preintervention) period and the 2-years intervention period will be compared with the use of an adjusted odds ratio (with 95% confidence intervals) for the interaction between group (intervention vs. control) and time period (intervention period vs. baseline).
5. The adjusted odds ratio for interaction will be estimated with the use of data on women who will deliver during the baseline period or the intervention period and will measure the intervention effect with the difference-in-differences approach, which is adapted for generalized-estimating equations analyses of clustered binary outcomes.

Key secondary outcome(s))
Measured at the mid and at the end of the 2-years intervention period
1. Major maternal morbidity rate
2. Minor perinatal morbidity rate
3. Minor maternal morbidity rate
4. Vaginal Birth After Cesarean rate

Completion date
30/09/2020

Eligibility

Key inclusion criteria
Hospital level:
1. Public hospitals with functional surgical rooms and high performance sonographic devices.
2. More than 300 deliveries per year
3. Written agreement to participate in the study from the directors of maternity services and professional services

Woman level (data collection):
1. All women with one prior cesarean delivery who delivered at participating centers and whose newborns had a gestational age of at least 22 weeks and weighed at least 500 g at delivery.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Hospital level:
1. Public hospitals with, at the time of recruitment, recent or ongoing quality-improvement programs specifically designed to target women with one prior cesarean delivery
Woman level (data collection):
2. Women that give birth or abort before 22 weeks of gestation

Date of first enrolment
01/04/2016

Date of final enrolment
13/12/2019

Locations

Countries of recruitment
Canada

Study participating centre
Hospital of Laval University (Centre hospitalier de l'Université Laval (CHUL))
2705, Boulevard Laurier
Québec
Canada
G1V 4G2

Sponsor information

Organisation
CHU de Québec Research Center

ROR
https://ror.org/006a7pj43

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

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		11/12/2023	15/12/2023	Yes	No
Protocol article	protocol	20/09/2017	15/01/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes