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Quality of care, obstetrical risk management and type of deliveries in Quebec (qualité des soins, gestion du risque obstétrical et du mode d'accouchement au Québec)

Submission date
23/10/2007

Recruitment status
No longer recruiting

Registration date
23/10/2007

Overall study status
Completed

Last Edited
24/05/2017

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-84657

Study information

Scientific Title
Quality of care, obstetrical risk management and type of deliveries in Quebec: a multicentre, two arm, randomised cluster trial

Acronym
QUARISMA

Study objectives
Primary hypothesis:
The QUARISMA program will result in a 20% reduction in the rate of caesarean section (CS) among the hospitals following the intervention compared to control hospitals.

Secondary hypotheses:
This program will result in:
1. A reduction in materno-foetal morbidity, including a reduction in severe morbidity among low risk patients.
2. No augmentation in materno-foetal morbidity among high risk patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Le comite d'ethique de la rechereche du CHU Ste-Justine, Montreal, QC (Canada), 15/10/2007, ref: #2604

Study design
Multicentre two-arm randomised cluster trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Information in English is not yet available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Caesarean section rate

Interventions
Audit Group Hospitals:
1. Society of Obstetricians and Gynaecologists of Canada provide training to health professionals (2 days at the year 2 and 1 day at the year 3)
2. Four self audit cycles with supervision by research team (3 months each), facilitated by a local opinion leader, starting at the sixth month of the second year for one year
3. Four other self audit cycles without supervision (3 months each) for another year

Control Group Hospitals:
Usual care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Caesarean section rate (total number of CS/total number of deliveries): data is collected every day from womens' clinical files during the 3.5 years of the program in the 32 hospitals (16 control and 16 interventions), to compare caesarean section rates in the intervention group with the rate in the control group at the end of the intervention period (year 3) and at the end of the follow-up period (year 4 or post intervention period).

Secondary outcome measures
Measured at the end of the intervention period (year 3) and at the end of the follow-up period (year 4 or post intervention period):
1. Caesarean section rate stratified by indications
2. Caesarean section rate stratified by type of CS (primary or repeat) and by the risk level of the delivery (high or low risk)
3. Vaginal birth after caesarean section rate
4. Obstetrical intervention rate
5. Maternal and neonatal morbidity

Overall study start date
01/04/2008

Completion date
31/10/2011

Eligibility

Key inclusion criteria
Hospital level:
1. Public hospitals with functional surgical rooms
2. More than 300 deliveries per year
3. A caesarean rate greater than or equal to 17%

4. Written agreement to participate in the study from the directors of maternity services and professional services

Woman level (data collection):
5. Women carrying a viable foetus more than 500 grams during the course of the study

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
32 hospitals

Key exclusion criteria
Hospital level:
1. Public hospitals with an existing intervention for reducing caesarean section

Woman level (data collection):
2. Women that give birth or abort before 24 weeks of gestation

Date of first enrolment
01/04/2008

Date of final enrolment
31/10/2011

Locations

Countries of recruitment
Canada

Study participating centre
CHU Sainte-Justine
Quebec
Canada
H3T 1C5

Sponsor information

Organisation

Sainte-Justine Hospital Research Center (Centre de recherche du CHU Sainte-Justine) (Canada)

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Sponsor type
Hospital/treatment centre

Website
http://www.recherche-sainte-justine.qc.ca/en/

ROR
https://ror.org/01gv74p78

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, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	30/04/2015		Yes	No
Results article	cost-effectiveness results	22/05/2017		Yes	No