

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 23/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/05/2017	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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 recherche du CHU Ste-Justine, Montreal, QC (Canada), 15/10/2007, ref: #2604

Primary study design

Interventional

Study design

Multicentre two-arm randomised cluster trial

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), 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

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