# 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	Recruitment status  No longer recruiting	<ul><li>[X] Prospectively registered</li><li>Protocol</li></ul>		
23/10/2007				
Registration date	Overall study status Completed	Statistical analysis plan		
23/10/2007		[X] Results		
Last Edited	Condition category	[] Individual participant data		
24/05/2017	Pregnancy and Childbirth			

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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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)

### Sponsor details

3175 Chemin Côte Ste-Catherine Montreal Quebec Canada H3T 1C5 +1 (0)514 345 4931 ext. 5657 sylvie.cossette.inf@umontreal.ca

#### 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 - 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**

Publication and dissemination plan

# Not provided at time of registration

# Intention to publish date

# 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