Improving perinatal care in Latin America

Submission date Prospectively registered Recruitment status 04/11/2004 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 25/02/2005 Completed [X] Results [] Individual participant data Last Edited Condition category 28/01/2019 Pregnancy and Childbirth

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00070720

Protocol serial number

GN 01

Study information

Scientific Title

A behavioral intervention to improve obstetrical care.

Acronym

GUIDELINES Trial

Study objectives

The aim of this trial is to evaluate the effect of a multifaceted behavioural intervention on the use of two evidence-based birth practices, the selective use of episiotomies and active management of the third stage of labor (injection of 10 International Units of oxytocin).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The protocol was submitted and approved by the IRBs of the following institutions:

- 1. University of North Carolina at Chapel Hill (USA)
- 2. Tulane University (USA)
- 3. Research Triangle Institute (USA)
- 4. Pan American Health Organization (USA)
- 5. School of Medicine of the University of the Republic in Uruguay (Uruguay)
- 6. The University Hospital of Montevideo (Uruguay)
- 7. The Argentinean Society for Clinical Research (Argentina)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Episiotomy use; post-partum haemorrhage

Interventions

Intervention group:

Evidence based clinical practice guidelines development workshop for opinion leaders. Opinion leaders will then use academic detailing, reminders, and feedback for dissemination and implementation of guidelines at the hospital level.

Control group:

Control hospitals will continue with their usual in-service training activities and will receive components of the intervention at the end of the study period.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Oxytocin

Primary outcome(s)

The rates of episiotomy and oxytocin use during the third stage of labor.

Key secondary outcome(s))

- 1. Perineal sutures
- 2. Postpartum haemorrhages
- 3. Birth attendants opinions

Completion date

01/09/2006

Eligibility

Key inclusion criteria

24 public hospitals in Argentina and Uruguay that had:

- 1. At least 1000 vaginal deliveries per year
- 2. No explicit policy for selective episiotomy or active management of third stage of labor

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not comply with above inclusion criteria.

Date of first enrolment

01/09/2003

Date of final enrolment

01/09/2006

Locations

Countries of recruitment

Argentina

United States of America

Uruquay

Study participating centre School of Public Health and Tropical Medicine

New Orleans, LA United States of America 70112

Sponsor information

Organisation

National Institute of Child Health and Human Development (NICHD) (USA)

ROR

https://ror.org/04byxyr05

Funder(s)

Funder type

Government

Funder Name

National Institute of Child Health and Human Development (NICHD) (USA)

Alternative Name(s)

NICHD

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Funder Name

Global Network for Women's and Children's Health Research (USA)

Funder Name

Bill and Melinda Gates Foundation (USA)

Alternative Name(s)

Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

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	01/05/2008	28/01/2019	Yes	No
<u>Protocol article</u>	protocol	11/04/2005		Yes	No