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Improving perinatal care in Latin America

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00070720

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
1. Perineal sutures
2. Postpartum haemorrhages
3. Birth attendants opinions

Overall study start date
01/09/2003

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

Age group
Adult

Sex
Female

Target number of participants
24 public hospitals

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

Uruguay

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)

Sponsor details
6100 Executive Boulevard
Room 4B05H
Rockville, MD
United States of America
20852
+1 301 402 0830
wrightl@mail.nih.gov

Sponsor type
Government

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, 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

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?
Protocol article	protocol	11/04/2005		Yes	No
Results article	results	01/05/2008	28/01/2019	Yes	No