ISRCTN43153145 https://doi.org/10.1186/ISRCTN43153145

Effect of high volume saline enemas during labour

Submission date	Recruitment status	[ ] Prospectively registered
20/03/2002	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/03/2002	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/10/2017	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

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of high volume saline enemas during labour: a randomised controlled trial

Study objectives
The main objective of this trial was to determine if the use of high volume enemas during the first stage of labour modified neonatal and/or puerperal infectious rates. The null hypothesis stated that infectious morbidity was similar for intervention and control groups. A secondary objective was to establish if there is any effect on specific neonatal or puerperal infectious rates and other clinically relevant outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Puerperal and neonatal infections

Interventions
Enema versus no enema. Block randomisation allocation with sealed envelopes.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcomes were infections in newborns and /or puerperal women. During the analysis, neonatal and puerperal infections were described individually and then amalgamated into a new outcome. This outcome was the 'combined maternal-neonatal outcome'.

A neonatal outcome was positive when during follow-up, any of the following clinical conditions were diagnosed : ocular infection (defined as purulent drainage in the eye after the sixth day of delivery); umbilical infection (foul smell with periumbilical erythema); skin infection (cellulitis or impetigo); respiratory tract infection (clinical diagnosis of lower or upper respiratory tract infection); intestinal infection; meningitis, sepsis or if the child had been prescribed systemic antibiotics during the first month of life.

Positive puerperal outcomes were registered when the mother had any of the following conditions diagnosed by a health care provider: any suture dehiscence, purulent effusion from the episiorraphy, urinary tract infection, pelvic inflammatory disease or vulvovaginitis. While hospitalised, participating women and newborns were visited on a daily basis. Throughout the process data were gathered by trained research assistants using standardised questionnaires. Formats were also used to register data retrieved from telephone calls, during hospitalisation, at follow-up visits and when any communication was established with participants, their families or health care providers.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/1997

Completion date
28/02/1998

Eligibility

Key inclusion criteria
1. Women attending labour ward at low risk for delivery
2. Greater than 36 week gestation
3. In labour
4. Cervix dilatation <8 cm

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
443

Key exclusion criteria
Clinical diagnosis of any systemic or gynaecological bacterial infection, use of systemic antibiotics during the week prior to admission, rupture of amniotic membranes or doubt of their integrity, and a cervical dilatation greater than or equal to 7 cm.

Date of first enrolment
01/02/1997

Date of final enrolment
28/02/1998

Locations

Countries of recruitment
Colombia

United States of America

Study participating centre
525 23rd St, NW
Washington
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Sponsor information

Organisation
INCLEN Trust (USA)

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Sponsor type
Research organisation

Website
http://www.inclentrust.org

Funder(s)

Funder type
Research organisation

Funder Name
International Clinical Epidemiology Network seed grant

Funder Name
Enemas donated by Baxter (without detailed knowledge of research protocol)

Funder Name
Own funds provided by Luis Gabriel Cuervo

Funder Name
Logistics by the School of Medicine at the Universidad Javeriana in Bogota

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	19/03/2006		Yes	No