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The Canadian preterm labour nitroglycerin trial

Submission date	Recruitment status	[_] Prospectively registered
26/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/03/2009	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.perinet.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MCT-41550

Study information

Scientific Title
Transdermal nitroglycerin to reduce the incidence of neonatal mortality in women who present in preterm labour: a placebo-controlled randomised trial

Study objectives
To determine if transdermal nitroglycerin (GTN), compared to placebo, reduces the incidence of neonatal mortality (and/or mortality) by prolonging pregnancy in women who present in preterm labour between 24 and 32 weeks gestation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board gave approval on the 9th March 1999

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
Preterm labour

Interventions
Patients receive a intravenous bolus of saline (500 - 1000 ml) prior to randomisation. They have 1 study patch (drug or placebo) placed and a second additional patch placed after one hour if ongoing uterine activity or further cervical changes. The patch or patches are replaced in 24 hours for a further 24 hours. Patient have maternal blood pressure monitoring every 10 minutes for one hour after a patch is placed. Antenatal corticosteroids and use of antibiotics are as per the centres protocol for patients in preterm labour.

Trial details received: 12 Sept 2005

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Neonatal morbidity and prenatal mortality

Secondary outcome measures
1. Randomisation to delivery interval
2. Incidence of preterm delivery less than 48 hours after initiation of treatment
3. Incidence of delivery within 7 days of commencement of treatment
4. Incidence of delivery prior to 34 weeks gestation
5. Frequency of chorioamnionitis in preterm delivery
6. Frequency of completed course of antenatal corticosteroids
7. Frequency of side effects

Overall study start date
04/05/2001

Completion date
30/08/2006

Eligibility

Key inclusion criteria
1. Greater than or equal to 24 to less than or equal to 32 weeks gestational age based on menstrual dates or earliest ultrasound scan
2. Preterm labour:
2.1. At least four painful uterine contractions per 20 minutes
2.2. Change in the cervix (change in bishop score or bishop score greater than or equal to 6)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
600

Key exclusion criteria
1. Any maternal (e.g. significant antepartum haemorrhage) or foetal (e.g. non-reassuring heart rate pattern) condition necessitating immediate delivery
2. Multiple gestations (i.e. twins, triplets etc.)
3. Premature prelabour rupture of the membranes (PPROM)

4. Intrauterine foetal demise or lethal foetal anomalies
5. Cervix dilated greater than 8 cm
6. Treatment with another agent within 24 hours
7. Previous enrolment in this trial
8. Known sensitivity to GTN
9. Failure to give consent

Date of first enrolment
04/05/2001

Date of final enrolment
30/08/2006

Locations

Countries of recruitment
Canada

Study participating centre
Clinical Research Centre
Kingston
Canada
K7L 2V7

Sponsor information

Organisation
Queen's University (Canada)

Sponsor details
828 West 10th Avenue
Kingston
Canada
K7L 3N6

Sponsor type
University/education

Website
http://www.queensu.ca/

ROR
https://ror.org/02y72wh86

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-41550)

Funder Name
Physicians' Services Incorporated Foundation (Canada)

Alternative Name(s)
PSI Foundation, PSI

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2007		Yes	No