

# The Canadian preterm labour nitroglycerin trial

<b>Submission date</b> 26/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/03/2009	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.perinet.org>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Graeme Smith

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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?
<a href="#">Results article</a>	results	01/01/2007		Yes	No