

# SELAN Trial: Structured Early Labour Assessment and care by Nurses

<b>Submission date</b> 01/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/02/2009	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

**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**  
MCT-59614

## Study information

**Scientific Title**

The effectiveness of a structured approach to assessment and care by nurses in early or latent phase labour: a randomised controlled trial

**Acronym**

SELAN

**Study objectives**

1. To evaluate the effectiveness of structured approach to assessment and care by nurses in early or latent phase labour
2. To compare the costs of the new approach to the costs of usual care

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Ethics Review Office of University of Toronto approved on the 4th August 2004

**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**

Pregnancy and labour

**Interventions**

Structured early labour care, defined as: nurses assessment of foetal position, emotional status, and pain, followed by individualised interventions, including: positioning techniques, cognitive-behavioural strategies, comfort measures, and anticipatory guidance.  
Control: usual care.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Spontaneous vaginal delivery, as recorded on the medical record.

**Secondary outcome measures**

1. Labour and birth without use of intrapartum analgesia/anaesthesia
2. Perineal trauma
3. Costs
4. Womens evaluation of their care

**Overall study start date**

01/10/2002

**Completion date**

30/09/2006

**Eligibility****Key inclusion criteria**

1. Nulliparous, live singleton foetus in cephalic position
2. Mothers aged 18 - 49 years old
3. No contraindications to labour
4. Competent to give informed consent or has a parent/guardian who is competent to give informed consent
5. Experiencing contractions but does not meet criteria for admission to labour and delivery unit

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

5000

**Key exclusion criteria**

1. Gestational age less than 34 weeks
2. Planned caesarean delivery
3. Undergoing or admitted for cervical ripening or induction of labour
4. Complications that necessitate admission to antepartum unit or labour and delivery unit
5. Likely to be transferred to labour and delivery with one hour
6. Has a doula or midwife providing continuous support
7. Already enrolled in labour/delivery management study and the study protocols are incompatible

**Date of first enrolment**

01/10/2002

**Date of final enrolment**

30/09/2006

## **Locations**

**Countries of recruitment**

Canada

**Study participating centre**

**155 College Street**

Toronto, Ontario

Canada

M5T 1P8

## **Sponsor information**

**Organisation**

University of Toronto (Canada)

**Sponsor details**

27 King's College Circle

Toronto, Ontario

Canada

M5S 1A1

research.services@utoronto.ca

**Sponsor type**

University/education

**Website**

<http://www.utoronto.ca/>

**ROR**

<https://ror.org/03dbr7087>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-59614)

## 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	28/08/2008		Yes	No