

SELAN Trial: Structured Early Labour Assessment and care by Nurses

Submission date 01/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 01/09/2005	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 23/02/2009	Condition category Pregnancy and Childbirth	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Ellen D. Hodnett

Contact details
155 College Street
Suite 215
Toronto, Ontario
Canada
M5T 1P8

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Spontaneous vaginal delivery, as recorded on the medical record.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

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)

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

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	28/08/2008		Yes	No