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SELAN Trial: Structured Early Labour Assessment and care by Nurses

Submission date 01/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/09/2005	**Overall study status** Completed	
Last Edited 23/02/2009	**Condition category** 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
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
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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?
Results article	results	28/08/2008		Yes	No