SELAN Trial: Structured Early Labour Assessment and care by Nurses

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Ellen D. Hodnett

Contact details

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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