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Randomised controlled trial of a decision aid for primiparous women making decisions about labour analgesia

Submission date
10/08/2004

Recruitment status
No longer recruiting

Registration date
21/09/2004

Overall study status
Completed

Last Edited
19/07/2010

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
Added 19/07/10:
Most women use some method of pain relief during labour. There is extensive research evidence available of pharmacological pain relief during labour; however this evidence is not readily available to pregnant women. Decision aids are tools that present evidence based information and allow preference elicitation.
We developed a decision aid for labour analgesia for primiparous women planning a vaginal delivery. The aim of the decision aid was to reduce decisional conflict (uncertainty regarding which option to use), increase labour analgesia knowledge, without increasing anxiety and increase satisfaction with decision making in regards to labour analgesia. We tested the effectiveness of the decision aid in a randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 19/07/10:
1. Central Sydney Area Health Service Ethics Review Committee (ref: X02-0247)
2. University of Sydney Human Ethics Committee (ref: 3419)

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Pregnancy

Interventions
Two interventions: decision aid (evidenced based booklet of labour analgesia) and audio decision aid (evidenced based booklet, and accompanying audio CD).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Decisional conflict (uncertainty about which preference to choose) will be assessed by the Decisional Conflict Scale which has established reliability, good psychometric properties and is short (16 items). It has been used to evaluate a range of decision aids .
2. Measures of knowledge and realistic expectations about labour analgesia options and the benefits and risks of these options will be specific to this project. Thus we will need to develop, and test these measures as part of the project.
3. Anxiety will be measured by the state component of the short Spielberger anxiety scale which

has been extensively used and validated [30,32]. We do not anticipate the decision aid will increase women's anxiety but it is important to document any changes in anxiety associated with the decision aid.
4. Satisfaction with analgesia decisions will be assessed using the Satisfaction with Decision Scale - a very brief six item scale with high reliability was developed specifically to assess satisfaction with health care decisions

Satisfaction with the decision and anxiety will be measured again at 1216 weeks postpartum. This interval was chosen to avoid the potential bias arising from questioning women still in the hospital who may feel a disloyalty to their caregivers by a critical appraisal and whose opinions have been shown to be more positive and short-lived than those obtained further out from the birth itself [34]. At that time we will also ask about exposure to the decision aid (to assess contamination), support during labour and use of pain relief methods prior to hospital admission. These issues will be further explored in the sample selected for in-depth interview.

Key secondary outcome(s))
Service utilisation outcomes:
The aim of the decision aid is to assist preference elicitation, and not to influence the direction of the decisions taken. Nevertheless, it is important to collect service utilisation and pregnancy outcome data so we will record and compare the pain relief methods used by women in all arms of the study, as well as recording and comparing rates of pregnancy complications and perinatal outcomes. The latter will be obtained (with informed consent) from the existing computerised obstetric database and include:
1. Medical or obstetric complications
2. Induction or augmentation of labour
3. Mode of delivery (vaginal, emergency or planned CS)
4. Enrolment to delivery interval
5. Gestational age
6. Birthweight
7. Apgar scores
8. Perinatal deaths
9. Neonatal Intensive Care Unit admission
10. Length of stay

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Primiparous women who are ≥36 weeks gestation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Women who will not have any choice about analgesia, for example planned caesarean section (eg breech, placenta praevia, HIV)
2. Planned epidural (eg symptomatic heart disease)
3. Contraindications to analgesia (e.g drug sensitivities, anticoagulants, thrombocytopaenia)

Date of first enrolment
01/09/2004

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Australia

Study participating centre
Building D02
Sydney
Australia
2006

Sponsor information

Organisation
Australian National Health and Medical Research Council (Australia)

ROR
https://ror.org/011kf5r70

Funder(s)

Funder type
Research council

Funder Name
National Health and Medical Research Council of Australia (Australia) (#253635)

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	08/04/2010		Yes	No
Protocol article	protocol	09/12/2004		Yes	No