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Improving care at the primary/secondary interface: a trial of community-based support in early labour

Submission date	Recruitment status	[ ] Prospectively registered
05/11/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/03/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/10/2014	Pregnancy and Childbirth	[ ] Record updated in last year

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
SDO/40/2003

Study information

Scientific Title

Acronym
ELSA (Early Labour Support and Assessment)

Study objectives
In some parts of the UK, women having their first baby have a 40-50% chance of having a caesarean section or instrumental (forceps or ventouse) delivery. These increasing rates are of concern to childbearing women, their families, and to the health services as they are associated with more ill health in women and their babies.
Some existing studies (which are small, or not very rigourous) have suggested that women who attend hospital very early in their labour are more likely to have a range of interventions including artificial rupture of membranes, epidurals, and caesarean and instrumental births. Some 10-33% of women admitted to delivery suite are not in labour, and do not need to be in hospital. This study will test these observations using a large randomised controlled trial. The aim is to examine whether or not a home visit by a community midwife when a pregnant woman thinks she may be in labour will have any impact on the rates of caesarean and other instrumental births, and other outcomes such as use of pain relief, the woman's views, and the health service resources used, compared with normal care. Women expecting their first baby, and whose pregnancy is progressing normally, will be told about the study during their pregnancy, by their own community midwife. If they are interested in participating, and after giving formal consent at around 32 weeks, they will be randomly allocated to one of two groups. Women in the intervention group will be offered a home visit by a community midwife when they think they are in labour, while women in the control group will be asked to telephone the hospital for advice and to go into delivery suite if advised, as is normal practice across the UK. The midwife doing the home visit will offer support to the woman including breathing and relaxation techniques, carry out an assessment to see how labour is progressing, and offer advice about the appropriate time to go to hospital. Information about the two groups will be gathered directly from the women themselves, in pregnancy and 6 weeks after birth, from hospital notes, and from the midwives involved in the study. This information will be used to compare the outcomes for women in the two groups, to examine their views, to calculate the costs to the health services, and to the families. It is already known that caesarean section costs the health services more than twice the cost of a normal birth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

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

Interventions
1. Intervention: support and assessment for nulliparous women at home in early labour by community midwives
2. Control: standard care which usually comprises telephone advice to attend the hospital delivery suite to determine whether labour has established

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Labour

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2005

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Healthy nulliparous women

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Mother and Infant Research Unit
Leeds
United Kingdom
LS2 9LN

Sponsor information

Organisation
NHS Service Delivery and Organisation Programme (SDO) (UK)

Sponsor details
NCCSDO
London School of Hygiene and Tropical Medicine
99 Gower Street
London
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WC1E 6AZ

Sponsor type
Government

ROR
https://ror.org/02wnqcb97

Funder(s)

Funder type
Government

Funder Name
NHS Service Delivery and Organisation R&D Programme (UK), Ref: SDO/40/2003

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