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A cluster randomised trial to investigate the use of a decision aid for the diagnosis of active labour in term pregnancy

Submission date
28/02/2008

Recruitment status
No longer recruiting

Registration date
27/03/2008

Overall study status
Completed

Last Edited
10/12/2008

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CZH/4/245

Study information

Scientific Title

Acronym
TELSiS

Study objectives
The primary aim of this study is to compare the effectiveness of a decision aid for diagnosis of active labour, with standard care in terms of maternal and neonatal outcomes, costs and costs savings. A secondary aim is to explore the impact of the intervention on women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Multicentre Research Ethics Committee for Scotland B (ref: 05/MRE10/31)

Study design
A cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Diagnosis of active labour

Interventions
Diagnosis of active labour using algorithm vs usual care (labour assessment by standard methods)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Use of oxytocin for augmentation of labour

Secondary outcome measures
1. Interventions in labour i.e. artificial rupture of membranes (ARM)
2. Vaginal examination (VE)
3. Use of analgesia
4. Mode of delivery
5. Management of women "not in labour"
6. Intrapartum complications
7. Neonatal outcome
8. Unplanned out-of-hospital births
9. NHS cost and cost to women

Overall study start date
31/03/2005

Completion date
30/06/2007

Eligibility

Key inclusion criteria
Women who were primiparous, at term, and assessed as low risk

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
4,800 (12 clusters, 400 women in each cluster)

Key exclusion criteria
1. Multiparous
2. Pre-term
3. Multiple pregnancy
4. Medical or obstetric complications
5. Under 16 years of age

Date of first enrolment
31/03/2005

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Iris Murdoch Building
Stirling
United Kingdom
FK9 4LA

Sponsor information

Organisation
University of Stirling (UK)

Sponsor details
-
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United Kingdom
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Sponsor type
University/education

Website
http://www.external.stir.ac.uk

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Health Service Research Committee, Scotland (UK)

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	08/12/2008		Yes	No