

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	<input type="checkbox"/> Prospectively registered
Registration date 27/03/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/12/2008	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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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Stirling

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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