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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
28/02/2008		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
27/03/2008	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
10/12/2008	Pregnancy and Childbirth			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Ms Helen Cheyne

#### Contact details

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# Additional identifiers

Protocol serial number 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

#### Study type(s)

Diagnostic

#### 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(s)

Use of oxytocin for augmentation of labour

# Key secondary outcome(s))

- 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

#### Completion date

# **Eligibility**

#### Key inclusion criteria

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

#### Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

### Age group

Adult

#### Sex

Female

#### 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

**United Kingdom** 

Scotland

## Study participating centre Iris Murdoch Building Stirling United Kingdom

FK9 4LA

# Sponsor information

## Organisation

University of Stirling (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**

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