

A randomised controlled trial investigating the effect of POSition IN LABour and effect on pudendal nerve physiology

Submission date 15/01/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 03/05/2007	Overall study status Completed	☐ Protocol
Last Edited 10/10/2014	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Protocol serial number

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Study information

Scientific Title

Acronym
POSINLAB

Study objectives

The hypothesis of the trial is that direct pressure on the pudendal nerve and or sacral plexus during the first stage of labour rather than traction on the pelvic floor during the second stage of labour is supported by previous observations of our research group. Firstly pudendal nerve latency has been consistently shown to be prolonged more on the left than on the right. Secondly caesarean delivery late in labour does not prevent changes in pudendal nerve terminal motor latency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the National Maternity Hospital, 12/09/2002.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pudendal nerve neuropathy

Interventions
It is proposed to randomise sixty primiparous women in the first stage of labour to conventional nursing on the left side or nursing on alternate sides every 30 minutes. Delivery would be in the left lateral position in group one and in the lithotomy position in group two.

Pelvic floor Electromyography (EMG), anorectal manometry and continence scoring would be performed at the six week postnatal check.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The effects on pudendal nerve motor latency

Key secondary outcome(s)
The difference in anorectal manometry and continence scoring between the groups

Completion date

30/06/2007

Eligibility

Key inclusion criteria

Primiparous healthy patients who are in labour with a single cephalic foetus

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Patients with a history of bowel symptoms or bowel surgery
2. Patients without fluent English
3. Diabetic patients
4. Patients attending the hospital High Risk Clinic

Date of first enrolment

01/02/2007

Date of final enrolment

30/06/2007

Locations

Countries of recruitment

Ireland

Study participating centre

UCD School of Medicine and Medical Science

Dublin

Ireland

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Sponsor information

Organisation

Health Research Board of Ireland (Ireland)

ROR

<https://ror.org/003hb2249>

Funder(s)

Funder type

Government

Funder Name

Health Research Board of Ireland (Ireland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration