

Randomised controlled trial of Early biofeedBAck PhysioTherapy versus pelvic floor exercises in patients who sustain third degree tears

Submission date 23/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/08/2011	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Colm O Herlihy

Contact details

UCD School of Medicine and Medical Science
National Maternity Hospital
Dublin
Ireland
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Additional identifiers

Protocol serial number

2

Study information

Scientific Title

Acronym

EBAPT

Study objectives

Women who sustain third or fourth degree tears are at risk of subsequent faecal incontinence. Our hypothesis is that women who sustain a third degree tear who have early intervention with home biofeedback physiotherapy will have fewer symptoms and better manometry pressures than those advised to perform standard pelvic floor exercises.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the National Maternity Hospital on the 21st January 2007

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anal sphincter injury leading to anal incontinence

Interventions

We propose to randomise patients who have sustained a third or fourth degree tear into two groups. One group receives current management of laxatives, antibiotics and analgesia and is advised on pelvic floor exercises. The other group is shown how to perform biofeedback exercises using a machine at home. Both groups will be followed up at the specialised perineal clinic and will be evaluated using endo-anal ultrasound and anorectal manometry.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Manometry scores at three months.

Key secondary outcome(s)

Symptoms and continence scores at three months.

Completion date

31/01/2008

Eligibility

Key inclusion criteria

Patients who have sustained a third degree tear in labour

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Patients who sustained a third degree tear in a previous delivery
2. Patients whose babies are in the special care baby unit
3. Infectious blood borne disease: Human Immunodeficiency Virus (HIV) and hepatitis B and C
4. Patients who have drug and alcohol addiction problems and would not be likely to be able to follow the home programme
5. Patients who do not have a fluent command of English

Date of first enrolment

01/02/2007

Date of final enrolment

31/01/2008

Locations**Countries of recruitment**

Ireland

Study participating centre

UCD School of Medicine and Medical Science

Dublin

Ireland

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Sponsor information**Organisation**

National Maternity Hospital (Ireland)

ROR

<https://ror.org/03jcxa214>

Funder(s)

Funder type

Government

Funder Name

National Maternity Hospital, 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