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

Submission date	Recruitment status	Prospectively registered
23/01/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
03/05/2007	Completed	Results
Last Edited	Condition category	Individual participant data
30/08/2011	Pregnancy and Childbirth	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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Manometry scores at three months.

Secondary outcome measures

Symptoms and continence scores at three months.

Overall study start date

01/02/2007

Completion date

31/01/2008

Eligibility

Key inclusion criteria

Patients who have sustained a third degree tear in labour

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

80

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

Study participating centre UCD School of Medicine and Medical Science Dublin Ireland 2

Sponsor information

Organisation

National Maternity Hospital (Ireland)

Sponsor details

Holles Street Dublin Ireland 2

Sponsor type

Hospital/treatment centre

Website

http://www.nmh.ie/Internet/

ROR

https://ror.org/03jcxa214

Funder(s)

Funder type

Government

Funder Name

National Maternity Hospital, Health Research Board of Ireland (Ireland)

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 summaryNot provided at time of registration