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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

Registration date
03/05/2007

Overall study status
Completed

Last Edited
30/08/2011

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] 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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UCD School of Medicine and Medical Science
National Maternity Hospital
Dublin
Ireland
2

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Ireland

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 summary

Not provided at time of registration