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BOD Trial: a double blinded randomised controlled trial of injection of botulinum toxin versus normal saline into the puborectalis muscle in patients with pelvic floor dyssynergia

Submission date
29/09/2006

Recruitment status
Stopped

Registration date
29/09/2006

Overall study status
Stopped

Last Edited
30/01/2014

Condition category
Nervous System Diseases

[ ] 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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Additional identifiers

EudraCT/CTIS number
2005-001378-29

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0050171996

Study information

Scientific Title

Study objectives
Botulinum Toxin injection into the pelvic floor muscles has been shown to be of benefit for patient whose muscles contract abnormally, causing difficulty in opening their bowels. However the studies that have shown this have all been small and have never been compared with a placebo. The difficulty in assessing the way patients respond to interventions when they have this condition may mean that the effect of the Botulinum injection is largely a placebo effect. The aim of this study is to assess the effect of the botulinum toxin injection compared with a placebo (saline). If it proves to be successful this will offer us a validated treatment in this difficult condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Nervous System Diseases: Pelvic floor dyssynergia

Interventions
The study aims to randomly assign ten patients to each treatment arm of the study. The patients will be selected from outpatient clinics after assessment has shown they have abnormal pelvic floor muscle contraction. They will complete a preoperative questionnaire containing a quality of life questionnaire, as well as specific questions on bowel function. After fully informed consent they will be randomised to receive either 30 unit Botulinum toxin A or an equivalent

volume of normal saline injection into the puborectalis muscle under anaesthetic with ultrasound guidance to ensure accuracy of placement of the injection into the correct pelvic floor muscle.

Updated 30/01/2014: the trial was never completed and was stopped in 2007/2008.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
botulinum toxin

Primary outcome measure
Improvement in quality of life.

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/09/2005

Completion date
31/08/2007

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
Potential participants in the study will be identified from the outpatient clinic after history examination and investigation suggest they have pelvic floor dyssynergia. They will be invited to take part in the trial after it has been explained to them. 20 participants will be recruited in to the study.

This standardised definition for pelvic floor dyssynergia was established at the multinational workshop for functional bowel disorders and is known as the Rome II criteria:
1. The patient must satisfy diagnostic criteria for functional constipation in diagnostic criteria C3.
2. There must be manometric, EMG, or Radiological evidence for inappropriate contraction or failure to relax the pelvic floor muscles during repeated attempts to defecate.
3. There must be evidence of adequate propulsive forces during attempts to defaecate.
4. There must be evidence of incomplete evacuation.
The key abnormality in this condition is the inappropriate contraction of the puborectalis muscle upon defecation.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
20

Key exclusion criteria
1. If the patient's general health is poor such that anaesthesia present unacceptably high risks they will be precluded from the trial (as it is inappropriate to subject these patients through the risk of anaesthesia for unproven intervention).
2. Patients who are anticoagulated will also be excluded because of the risk of haematoma formation.

Date of first enrolment
16/09/2005

Date of final enrolment
31/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bradford Royal Infirmary
Bradford
United Kingdom
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
Bradford Teaching Hospitals NHS Foundation Trust

Funder Name
Bradford Royal Infirmary

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