ISRCTN34920540 https://doi.org/10.1186/ISRCTN34920540

Injectable silicone biomaterial (PTQTM) is more effective than carbon-coated beads (Durasphere®) in treating passive faecal incontinence: a randomised trial

Submission date
22/05/2008

Recruitment status
No longer recruiting

Registration date
09/06/2008

Overall study status
Completed

Last Edited
10/06/2008

Condition category
Signs and Symptoms

[ ] 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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
To compare safety and efficacy of PTQTM compared with Durasphere® in treating patients with passive faecal incontinence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Human Resource Ethics Committee of Epworth Hospital

Study design
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
Passive faecal incontinence

Interventions
Injectable bulking agents to augment the bulk of the internal anal sphincter: injectable silicone biomaterial (PTQTM) vs carbon-coated beads (Durasphere®).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

PTQTM, Durasphere®

Primary outcome measure
Wexners continence score, assessed at 2 and 6 weeks, then 6 and 12 months after treatment

Secondary outcome measures
The following were assessed at 2 and 6 weeks, then 6 and 12 months after treatment:
1. Faecal incontinence quality of life (FIQL) scale
2. Short Form 12 (SF-12) health survey questionnaire
3. Adverse events

Overall study start date
01/08/2005

Completion date
31/10/2006

Eligibility

Key inclusion criteria
1. Both males and females, no age limits
2. Faecal seepage or soiling for more than twice a week caused by internal sphincter (IAS) dysfunction
3. Not responding to treatment with dedicated pelvic floor exercises and stool bulking agents

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Perianal sepsis
2. Anorectal cancer
3. Immunosuppression
4. Rectal prolapse
5. Inflammatory bowel disease
6. Congenital anorectal malformation
7. Neurological disorders such as Parkinsons disease
8. Multiple sclerosis
9. Spinal-cord injury
10. Stoma in situ
11. Pregnancy
12. External anal sphincter defect of more than 120° of the circumference

13. Bleeding diathesis,
14. Mental or physical disability precluding adherence to study protocol

Date of first enrolment
01/08/2005

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
Australia

Hong Kong

Study participating centre
Caritas Medical Centre, 111
Hong Kong
Hong Kong
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Sponsor information

Organisation
Epworth Hospital, University of Melbourne (Australia)

Sponsor details
89 Bridge Road
Richmond
Melbourne
Australia
3121

Sponsor type
University/education

Website
http://www.epworth.org.au

ROR
https://ror.org/01ej9dk98

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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