

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

<b>Submission date</b> 22/05/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 09/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 10/06/2008	<b>Condition category</b> Signs and Symptoms	<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

Dr Miranda Chan

### Contact details

Caritas Medical Centre, 111  
Wing Hong Street  
Shum Shui Po  
Hong Kong  
Hong Kong

-

+852 3408 7785

mirchan@hotmail.com

## 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 PTQ™ 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 (PTQ™) 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

-

## **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