

# An oestrogen cream for the treatment of faecal incontinence

<b>Submission date</b> 22/01/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 16/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 16/05/2008	<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**  
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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Are topical oestrogens useful in faecal incontinence? A double blind randomised trial

**Study objectives**  
A topical application of oestrogens is effective for the symptoms of faecal incontinence in post-menopausal women.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics approval received from the Comité de ética Pontificia Universidad Católica de Chile on the 3rd April 2007 (ref: C.E. #095/07).

## **Study design**

Double blind, randomised, placebo-controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Faecal incontinence

## **Interventions**

Application of topical estriol (Ovestin®) or placebo according to the randomisation. The cream was applied in the anal canal mucosa three times a day (tid) during six weeks. Dosage approximately 1 g every eight hours.

The total duration of follow-up of all patients was six weeks.

## **Intervention Type**

Drug

## **Phase**

Not Specified

## **Drug/device/biological/vaccine name(s)**

Estriol (Ovestin®)

## **Primary outcome(s)**

The degree of continence was evaluated by Wexner's FI score at the beginning and end of the protocol (six weeks since the beginning).

## **Key secondary outcome(s)**

In order to evaluate the degree of impact on quality of life, we used a quality of life questionnaire validated and accepted for the Spanish language (ECIF), at the beginning and end of the protocol (six weeks since the beginning).

## **Completion date**

01/07/2007

## **Eligibility**

### **Key inclusion criteria**

1. Post-menopausal women (at least 1 year) without hormonal substitution
2. Aged 69 years  $\pm$  8 (treatment group) and 66 years  $\pm$  8 (placebo group)
3. Wexner's faecal incontinence (FI) score greater than 5
4. Anal ultrasound with less than 50% damage to external sphincter
5. Accepted informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

1. Perianal lesions
2. History of endometrial, breast or cervix cancer
3. Allergy to oestrogens

**Date of first enrolment**

01/06/2006

**Date of final enrolment**

01/07/2007

**Locations****Countries of recruitment**

Chile

**Study participating centre**

Marcoleta 350 patio interior

Santiago

Chile

8330033

**Sponsor information****Organisation**

Pontifical Catholic University of Chile (Pontificia Universidad Catolica de Chile) (Chile)

ROR

<https://ror.org/04teye511>

## Funder(s)

### Funder type

University/education

### Funder Name

Pontifical Catholic University of Chile (Pontificia Universidad Catolica de Chile) (Chile) -  
Department of Digestive Surgery (Departamento de Cirugia Digestiva)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration