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An oestrogen cream for the treatment of faecal incontinence

Submission date	Recruitment status	[ ] Prospectively registered
22/01/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/05/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/05/2008	Signs and Symptoms	[ ] 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

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 Comite de etica Pontificia Universidad Catolica de Chile on the 3rd April 2007 (ref: C.E. #095/07).

Study design
Double blind, randomised, placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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).

Overall study start date
01/06/2006

Completion date
01/07/2007

Eligibility

Key inclusion criteria
1. Post-menopausal women (at least 1 year) without hormonal substitution
2. Aged 69 years ± 8 (treatment group) and 66 years ± 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

Age group
Adult

Sex
Female

Target number of participants
34 patients

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)

Sponsor details
Departamento de Cirugia Digestiva
Marcoleta 350 patio interior
Santiago
Chile
8330033

Sponsor type
University/education

Website
http://www.puc.cl/

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

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