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Zinc-aluminium ointment for patients with faecal incontinence

Submission date	Recruitment status	[ ] Prospectively registered
05/11/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/12/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/12/2010	Digestive System	[ ] 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

Zinc-aluminium ointment for patients with faecal incontinence: a double blind randomised trial

Acronym
ZAOT

Study objectives
The use of Zinc-aluminium (Zn-Al) ointment improve the continence in patients with faecal incontinence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the Pontificia Universidad Catolica de Chile approved on the 1st April 2008 (ref: 109/08)

Study design
Double blind randomised placebo controlled phase II 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
Treatment group:
Topical application of ointment in the perianal region for 4 weeks. Ointment consists of Aluminum Sulphate (0.5%), Zinc Sulphate (0.1%), Benzocaine (0.05%), Clorhexidine (0.09%) and Titanium Dioxide (0.1%)

Placebo group:
Topical application of Novobase II in the perianal region for 4 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Zinc-aluminium ointment

Primary outcome measure
Wexner Score, measured at baseline and 4 weeks

Secondary outcome measures
Faecal Incontinence Quality of Life (FIQL) score, measured at baseline and 4 weeks

Overall study start date
10/03/2010

Completion date
24/04/2010

Eligibility

Key inclusion criteria
1. Female
2. Aged 18 years or older
3. Consulted the outpatient clinic in the Colorectal unit of Pontificia Universidad Catolica de Chile
4. Faecal incontinence
5. Wexner Score greater than or equal to 7
6. Minima sphincter disruption in anal endosonography
7. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
50 patients

Key exclusion criteria
1. Male
2. Sphincter disruption greater than 50%

Date of first enrolment
10/03/2010

Date of final enrolment
24/04/2010

Locations

Countries of recruitment
Chile

Study participating centre
Marcoleta 367
Santiago
Chile
-

Sponsor information

Organisation
Pontifical Catholic University of Chile (Pontificia Universidad Católica de Chile) (Chile)

Sponsor details
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Sponsor type
University/education

Website
http://www.uc.cl/

ROR
https://ror.org/04teye511

Funder(s)

Funder type
University/education

Funder Name
Pontifical Catholic University of Chile (Pontificia Universidad Católica de Chile) (Chile) - Surgical Department

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