

Zinc-aluminium ointment for patients with faecal incontinence

Submission date 05/11/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/12/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/12/2010	Condition category Digestive System	<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

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Additional identifiers

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

Study type(s)

Treatment

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(s)

Wexner Score, measured at baseline and 4 weeks

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

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Sponsor information

Organisation

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

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration