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

Contact name

Dr George Piendo

Contact details

Marcoleta 367 Santiago Chile

C

gpinedom@hotmail.com

Additional identifiers

Protocol serial number

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

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

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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes