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A phase III, single-blind trial to assess efficacy and tolerability of genital mucosa after use of product INC056

Submission date	Recruitment status	[X] Prospectively registered
18/07/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/08/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/08/2008	Urological and Genital Diseases	[_] 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
INC056-01

Study information

Scientific Title
A phase III, single-blind, single-centre trial to assess efficacy and tolerability of genital mucosa after use of product INC056 in post-menopausal women

Study objectives
This study is to confirm the safety, tolerability and efficacy of INC056 in post-menopausal female volunteers.

Hypothesis:
This treatment is expected to lower the vaginal pH in post-menopausal women and thus, to relieve local irritability and dryness of vagina.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval received from the Ethics Committee of Irmandade de Misericórdia de Campinas - Hospital Irmãos Penteado (Brazil) on the 10th December 2007

Study design
A phase III, single-centre, non-randomised, non-controlled, single-blind study

Primary study design
Interventional

Secondary study design
Non 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
Local irritability and dryness of vagina

Interventions
Pre-trial visit:
Prior to interventions, written informed consent will be gained. Screening assessment, vaginal pH testing, gynaecological exam and interview will be performed. The dose is one disposable applicator full of INC056 product (approximately 4 grams), applied intravaginally at bedtime.

Volunteers will be instructed to administrate the product as following:
1. Once every 3 days during 30 days
2. A 7 days washout period
3. Once daily for next 14 days

Visits will be performed on days 15, 30, 37 and 53.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
INC056

Primary outcome measure
Evaluate vaginal acidification after product use (lowering of vaginal pH) at all visits (baseline and days 14, 30, 37 and 52).

Secondary outcome measures
The following will be assessed at all visits (baseline and days 14, 30, 37 and 52):
1. Assessment of all adverse events reported
2. Assessment of vaginal dryness and/or sexual discomfort
3. Occurrence of recurrent vaginal infections in volunteers
4. Investigator's Global Assessment
5. Volunteer's Global Assessment
6. Assessment measured by acceptability questionnaire
7. Interruption of use due allergic reactions or irritability

Overall study start date
01/10/2008

Completion date
01/02/2009

Eligibility

Key inclusion criteria
1. Healthy female volunteers aged between 40 and 65 years
2. Post-menopausal women
3. Vaginal pH of 5.0 or higher
4. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
65 volunteers

Key exclusion criteria
1. Pregnancy or lactation
2. Skin disease at site of administration
3. Diabetes mellitus
4. Immunological insufficiency
5. Use of systemic corticoid, antibiotics or steroids
6. Use of immunosuppressive drugs
7. Skin diseases: vitiligo, psoriasis, lupus, atopic dermatitis
8. Antifungal therapy within the last month at screening
9. History of infection at the site of drug administration
10. History of allergies to components of product
11. Other diseases or medications that could interfere with the research result or endanger the volunteer

Date of first enrolment
01/10/2008

Date of final enrolment
01/02/2009

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Vicente Porto, 660.
Campinas
Brazil
13085-080

Sponsor information

Organisation
Incrementha PD&I (Brazil)

Sponsor details
Av. Professor Lineu Prestes, 2242
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Sponsor type
Industry

Website
http://www.incrementha.com.br

Funder(s)

Funder type
Industry

Funder Name
Incrementha PD&I (Brazil)

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