

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

<b>Submission date</b> 18/07/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/08/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/08/2008	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **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**

Incrementtha PD&I (Brazil)

## Funder(s)

**Funder type**

Industry

**Funder Name**

Incrementtha PD&I (Brazil)

## Results and Publications

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

Not provided at time of registration