

Effects of a natural ingredient-based vaginal gel on vaginal health

Submission date 01/02/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/02/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 14/11/2022	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cervical ectopy is a benign (harmless) condition that causes the delicate cells that line the cervix (birth canal) to be found on the surface outside of the cervix. This can be caused by childbirth, sexual intercourse and birth control use. For the majority of women this does not cause any problems but it can lead to higher amounts of vaginal discharge (mucous) and to bleeding after sexual intercourse. In order for this condition to be treated, a colposcopy (a procedure where the inside of the cervix is examined using a special microscope with a light (a colposcope)) is used to freeze or cauterise (burn) the cells. However, the ectopic tissue can reoccur therefore alternative treatment can be helpful. Palomacare® is a gel which acts as a moisturiser and can help repair cells. This study evaluates if Palomacare® gel can help to treat cervical ectopy and improve vaginal health in women.

Who can participate?

Women aged 18-45.

What does the study involve?

Participants attend a routine gynaecological visit (where they have a vaginal examination and colposcopy) and are then instructed on how to correctly use a vaginal gel called Palomacare® every day at bedtime for 12 days. Participants are followed up with a vaginal examination and colposcopy after 12 days to evaluate vaginal health.

What are the possible benefits and risks of participating?

Participants may benefit from improvements in their vaginal health. There are no notable risks to participants.

Where is the study run from?

Instituto Palacios de Salud y Medicina de la Mujer (Spain)

When is the study starting and how long is it expected to run for?

December 2014 to April 2015

Who is funding the study?
Procure Health (Spain)

Who is the main contact?
Dr Santiago Palacios

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Paloma15/1

Study information

Scientific Title

Beneficial effects of a *Coriolus versicolor*-based vaginal gel on cervical epithelization, vaginal microbiota and vaginal health: A pilot study in asymptomatic women

Study objectives

The aim of this study is to assess the clinical benefits of *Coriolus versicolor*-based vaginal gel (Palomacare®) on epithelization of cervical lesions and to improve vaginal microbiota and vaginal health in asymptomatic healthy women.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study does not require ethical approval. According to Spanish regulations ethics approval is not required for studies with the following characteristics: real life, pilot study, with a medical device (not a drug) class I already marketed and used within approved indication, and sponsored by the principal investigator and not by a private pharmaceutical company.

Study design

Observational open-label single cohort prospective pilot clinical study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See additional files (Spanish)

Health condition(s) or problem(s) studied

Asymptomatic women with ectopia and alterations of the vaginal microbiota

Interventions

Participants attend a routine gynecological visit where they have a vaginal examination and a colposcopy to evaluate their symptoms. They are instructed on how to correctly use the vaginal gel Palomacare® once day at bedtime for 12 days.

Palomacare® is a non-hormonal (hyaluronic acid, β -glucan, alpha-glucan oligosaccharide, *Coriolus versicolor*, Asian centella, *Azadirachta indica* and Aloe vera) gel that acts a moisturiser and lubricant because of strong hydrating properties, also enhancing and accelerating repair of atrophic or injured cervicovaginal mucosa.

Participants are followed up 12 days after the treatment at the gynecological with a vaginal examination and a colposcopy to assess their vaginal health and microbiota.

Intervention Type

Supplement

Primary outcome measure

Degree of epithelization of the cervical mucosa is evaluated by standard colposcopy and rated by the the investigator using the ectopy ephithelization score at baseline and 12 days.

Secondary outcome measures

1. Vaginal microbiota is evaluated using the Vagina Status-Diagnostic test (Instiüt für Mikroökologie, Herborn, Germany) and further rated by the investigator using a 5-point Liker scale at baseline and 12 days
2. The vaginal health is assessed by the Bachmman Vaginal Health Index at baseline and 12 days

Overall study start date

01/12/2014

Completion date

01/04/2015

Eligibility**Key inclusion criteria**

1. Women aged between 18 and 45 years old
2. No signs and symptoms of vaginal disease
3. Normal Papanicolaou smear

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

21

Total final enrolment

21

Key exclusion criteria

1. Vaginal infections
2. Use of vaginal products other than the investigational compound
3. Being pregnant or breastfeeding.
4. History or concomitant diseases who are deemed to be ineligible by the investigator

Date of first enrolment

01/02/2015

Date of final enrolment

01/03/2015

Locations

Countries of recruitment

Spain

Study participating centre

Instituto Palacios de Salud y Medicina de la Mujer

C/ Antonio Acuña 9

Madrid

Spain

28009

Study participating centre

Clínica Sagrada Família

Torras i Pujalt, 1

Barcelona

Spain

08022

Sponsor information

Organisation

Instituto Palacios de Salud y Medicina de la Mujer

Sponsor details

Antonio Acuña 9

Madrid

Spain

E-28009

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/01kvepn75>

Funder(s)

Funder type

Industry

Funder Name

Procare Health

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

01/09/2016

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study is not expected to be made available due to confidentiality reasons.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		07/02/2017	21/02/2017	No	Yes
Results article		16/03/2017	29/01/2019	Yes	No