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

Submission date	Recruitment status	[_] Prospectively registered
01/02/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/02/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/11/2022	Urological and Genital Diseases	

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?
Procare Health (Spain)

Who is the main contact?
Dr Santiago Palacios

Contact information

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Public

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Additional identifiers

Protocol serial number
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.

Primary study design
Observational

Study design
Observational open-label single cohort prospective pilot clinical study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asymptomatic women with ectopia and alterations of the vaginal microbiota

Interventions
Participants attend a routine gyneacological 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, ß-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 gyneacological with a vaginal examination and a colposcopy to assess their vaginal health and microbiota.

Intervention Type
Supplement

Primary outcome(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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

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C/ Antonio Acuña 9
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Study participating centre
Clínica Sagrada Família
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Sponsor information

Organisation
Instituto Palacios de Salud y Medicina de la Mujer

ROR
https://ror.org/01kvepn75

Funder(s)

Funder type
Industry

Funder Name
Procare Health

Results and Publications

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?

Results article	16/03/2017	29/01/2019	Yes	No
Participant information sheet	07/02/2017	21/02/2017	No	Yes