

# Evaluating the effect of a non-hormonal vaginal gel on the cervix and vagina of HPV-positive women

<b>Submission date</b> 01/03/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/12/2020	<b>Condition category</b> Infections and Infestations	<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

### Background and study aims

The aim of the study was to evaluate the effect of the vaginal application of the Papilocare® gel on different aspects related to your vaginal health, among others, on the regeneration of the cervical mucosa and the state of the vaginal flora, of women with presence of human papillomavirus, but no lesion visible on colposcopy.

### Who can participate?

Sexually active women, 25 years of age and older, attending a routine control gynecologic visit, infected with human papillomavirus but with normal results in cytology and colposcopy.

### What does the study involve?

All participants received the same treatment, Papilocare, a non-hormonal vaginal gel once daily for 21 consecutive days, preferably at bedtime

### What are the possible benefits and risks of participating?

Possible benefits: improving both the regeneration of the cervical mucosa and the state of the vaginal flora. These effects improve your vaginal health.

No important risks were expected.

### Where is the study run from?

Service of Gynaecology, Policlínico HM Gabinete Velázquez, Madrid, Spain. Vagina flora samples were evaluated in CIBER-EHD, Department of Pharmacology, University of Granada, Spain.

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

July 2016 to January 2017.

Who is funding the study?

Work time dedicated to this study by University of Granada personnel falls within funds from Regional Government of Andalucía and by the Spanish Ministry of Economy and Competitiveness with funds from the European Union.

Procare Health SL (Castelldefels, Barcelona, Spain), owner of Papilocare provided logistic support for the study but had no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Who is the main contact?

Julio Galvez

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

EPI001

## Study information

**Scientific Title**

Effect of a Coriolus versicolor-based vaginal gel on cervical epithelization and vaginal microbiota in HPV-positive women with normal cytology and colposcopy: a pilot study

**Acronym**

Epicervix

### **Study objectives**

Evaluating the impact of the non-hormonal vaginal gel Papilocare® on cervical epithelization and the composition of vaginal microbiota in HPV-positive women with normal cytology and colposcopy.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approval of the study protocol by the institutional review board was not required because according to the Spanish law (Real Decreto 1591/2009, de 16 de octubre, por el que se regulan los productos sanitarios. Ministerio de Sanidad y Política Social «BOE» núm. 268, de 6 de noviembre de 2009 Referencia: BOE-A-2009-17606. TEXTO CONSOLIDADO. Última modificación: 25 de julio de 2013), studies with a medical device class I (not a drug) already marketed and used within approval indications are exempted.

### **Study design**

A non-comparative, open-label, prospective, and pilot study

### **Primary study design**

Observational

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Human papillomavirus infection

### **Interventions**

Women who gave consent to participate in the study and met the inclusion criteria were advised on the appropriate use of the vagina gel product Papilocare®. Participants were visited at baseline (screening) (visit 1, inclusion in the study) and after 21 days of treatment (visit 2). In both visits, the degree of epithelization was assessed by colposcopy and samples were obtained to determine the composition of the vaginal microbiota. Recruitment period started in July 2016. The total duration of the study was from July 2016 to January 2017.

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Primary outcome(s)**

The epithelization degree of the cervical mucosa was assessed by the investigator by standard colposcopy and rated using a 5-point Likert scale, where 5 was no ectopy, 4: mild (<25% of the external os), 3: moderate (25–50% of the external os), 2: severe (>50% of the external os) and 1: severe ectopy and bleeding. This variable was measured at baseline and 21 days.

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

The composition of bacterial communities was assessed by calculating three major ecological parameters, including the Chao1 richness index for abundance data (an estimate of a total community), the Pielou's evenness index (to show how evenly the individuals in the community were distributed over different operational taxonomic units [OUT]), and the Shannon biodiversity index (a combined parameter of richness and evenness) [34]. The Shannon biodiversity index was categorized as < 2 (low diversity), 2-3 (normal), and > 3 (high diversity). This variable was measured at baseline and 21 days.

**Completion date**

31/01/2017

## Eligibility

**Key inclusion criteria**

1. Sexually active women
2. 25 years of age and older
3. Attending a routine control gynecologic visit
4. Normal Papanicolaou smear and normal colposcopic findings
5. Diagnosis of HPV positivity by polymerase chain reaction (PCR)-based HPV DNA detection within 3 months before consultation.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Total final enrolment**

21

**Key exclusion criteria**

1. Clinically relevant disorders of the immune system
2. Treatment with immunosuppressant agents
3. Abnormal vaginal bleeding (without diagnosis) within the 6 months prior to the screening visit
4. Symptomatic vulvovaginal infection
5. History of gynecologic cancer
6. Use of vaginal contraceptives or other vaginal hormonal treatments
7. Planned surgery preventing compliance with treatment
8. Current participation in a current clinical trials or in the previous 4 weeks
9. Fertile women not using effective contraceptive methods
10. Pregnant or breastfeeding
11. Contraindication for the use of Papilocare® or known allergies to some of its components.

**Date of first enrolment**

10/07/2016

**Date of final enrolment**

05/01/2017

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

**Service of Gynecology, Policlínico HM Gabinete Velázquez**

orge Juan Street, 19 - 1 °, 28001 Madrid

Madrid

Spain

28001

## Sponsor information

**Organisation**

Gabinete Médico Velázquez SL

## Funder(s)

**Funder type**

Government

**Funder Name**

Ministerio de Economía y Competitividad

**Alternative Name(s)**

Ministry of Economy and Competitiveness, MINECO, MEC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Spain

## Funder Name

Junta de Andalucía

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as patient names were included in the dataset.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		22/03/2019	02/04/2019	No	Yes