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

Submission date
01/03/2019

Recruitment status
No longer recruiting

Registration date
02/04/2019

Overall study status
Completed

Last Edited
11/12/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
jgalvez@ugr.es

Contact information

Type(s)
Scientific

Contact name
Prof Maria Elena Rodriguez-Cabezas

ORCID ID
http://orcid.org/0000-0001-9085-8147

Contact details
Centre for Biomedical Research, University of Granada, Avenida del Conocimiento s/n
Granada,
Spain
18016
+34-958-241793
merodri@ugr.es

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional file.

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/07/2016

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

Age group
Adult

Sex
Female

Target number of participants
21 women

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

Sponsor details
Jorge Juan Street, 19 - 1 °
Madrid
Spain
28001
915 77 77 73
lsanchezgonzalez@hmhospitales.com

Sponsor type

Hospital/treatment centre

Website
http://www.gabinetemedicovelazquez.com/index.php/en/#

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

Publication and dissemination plan
We plan to publish the results in the BMC Women's Health Journal.

Intention to publish date
20/07/2019

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?
Participant information sheet		22/03/2019	02/04/2019	No	Yes