

Prevention and treatment of HPV-induced lesions

With over 150 types identified, human papillomavirus (HPV) is a virus that replicates exclusively in the epithelial cells and is transmitted by direct contact with the skin and/or mucous membranes. HPV infection is one of the most common sexually transmitted diseases, given that most sexually active people, including both men and women, will become infected at least once during their life.

Specifically, 30 to 50 percent of women in Spain aged under 30 years old will be HPV positive at some point. Despite this, most of these infections are temporary, which the immune system resolves unaided and without complications.

Two types of HPV can be differentiated: low risk, which cause warts in regions such as the genitals, or on the palms of the hands or the soles of the feet; and high risk, which are responsible for most high grade cervix lesions and 90 percent of cervical cancer cases.

It is estimated that 42 percent of the cervix lesions required to develop cancer do not clear up unaided among women infected with high risk HPV within a 2 year period. In fact, cervical cancer affects around 2,500 women in Spain a year, being the fourth cause of death among women aged 15 to 44 years old in the country.

As a Spanish pharmaceutical laboratory specialised in female health, Procure Health has been leading a line of investigation in conjunction with the Harvard Medical School and the University of California Los Angeles (UCLA) since 2018, which has led to the creation of the *cervix-on-a-chip*, i.e. a human cervix on a *chip*.

This instrument has been developed from investigation using human cells in order to discover new therapies and enables the study of the cervix transformation zone, which is particularly vulnerable to viral attacks during infection.

With the collaboration of Dr Danial Khorsandi from the UCLA Department of Bioengineering, this project lays the foundations for an unprecedented health and technological development that aims to help improve the lives of a large percentage of the population and will offer a greater understanding of the virus' integration into cervix cells and the mechanisms used for defence.

We also launched an innovative treatment called Papilocare in 2016. It is the first and only product indicated for preventing and treating Human Papillomavirus induced low grade cervix lesions for the European market. Its use avoids progression to high grade lesions and potentially developing cervical cancer.

Papilocare is a single use vaginal gel in cannulas that has already shown evidence for its efficacy in the Paloma clinical trial, the results of which were presented this autumn during several highly prestigious European congresses in the sector¹⁻⁴.

This trial recruited 101 patients and provided evidence for restoring low grade cervix lesions (ASCUS/LSIL) among 85 percent of treated patients at 6 months compared to 65 percent for the control group. This result was even more significant among women infected with high risk HPV, restoring lesions in 88 percent of patients *versus* 56 percent for the control group.

Furthermore, this result is very consistent with the 3 results presented by independent studies carried out by public teaching hospitals in Spain, who report an efficacy of 50 to 70 percent for 'Papilocare' when clearing high risk HPV.

However, the company's commitment to investigation and creating scientific and clinical evidence goes much further. This has led to the initiation of several clinical trials and studies, which include: the *Paloma 2 trial*, with 288 patients in 9 public and private centres in the country; the *Papilocan trial* versus placebo, undertaken with 200 patients by Hospital de La Candelaria (Santa Cruz de Tenerife); and the PapiOBS study, with 500 patients recruited from several European countries.

Up to now, patients with low grade HPV-induced lesions did not have an effective non-invasive treatment for them.

Thanks to Papilocare and the evidence for its efficacy, a new window opens for direct action, helping your body to eliminate these lesions.

Yann Gaslain

CEO of Laboratorios Procare Health

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