Observational study: effects of a topical preparation with Ozoile® (Vulvovagi®) in low-grade Papillomavirus (HPV) positive women.

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The therapy of the forms of ASCUS, and of cellular anomalies referable to the low-grade HPV virus to today is normally based on the use of immunostimulants; in variable percentages we observe a spontaneous negativization, independent of particular therapeutic strategies. The aim of the monocentric study was to evaluate the ability to negativize a high percentage of pap-positive women with low grade HPV, with preparation with Ozoile® (ozonized oil in oleic acid and vitamin E).

Papilloma Virus * (HPV), a genus of the Papovavirus family, is a widespread pathogenic human virus that is transmitted by sexual means. The infection can cause the onset of diseases of the skin and mucous membranes. An example is a cervical lesion. Most of these cervical lesions heal spontaneously, but some, if left untreated, progress slowly towards tumors (cervix carcinoma).

Method and overview

In oncological gynecology clinics, located at the ASL N.1 of Sassari (San Camillo Hospital), diagnostic tests (Pap tests) and vaccinations are carried out on the female population interested in the prevention of cervical cancer caused by the virus HPV (high risk genotypes).

Once the pap tests have been carried out, the samples are sent to be analyzed at the Institute of Pathological Anatomy, where, by measuring any cellular anomalies, there can be two results, positive or negative.

The reports are read, and according to the various anomalies present, usually always linked to the positivity for HPV (ASCUS, non-specific alterations of the cervical cells; CIN-1, CIN-2, mild dysplasia; CIN-3, severe dysplasia or carcinoma in situ), a more thorough search of the virus itself is performed by sampling for HPV-DNA test, and is sent for analysis at the Institute of Infectious Disease. Gynecologists then report to patients whether HPV will be high grade, low grade or mixed according to the various isolated genotypes. Low-grade positivity is frequently found, for which the recommended therapy consists of administering various types of immunostimulants and in this specific case of Vulvovagi®Spray, a medical device with Ozoile® (ozonized oil in oleic acid and vit.E), glyceric acid and Tea Tree Oil (melaleuca oil). The vaccine was recommended to all patients.

The reason for the use of a product such as Vulvovagi®Spray arises from some evidence in the literature (eg an independent experience that highlighted an excellent result of ozone derivatives in aqueous solution blown into the vagina, ed) in women positive for HPV, and from the recognized clinical results of treatment with Vulvovagi®Spray in patients suffering from vulvovaginitis of various origins. The stable ozonides that are present in Ozoile®, have demonstrated an excellent antibacterial, fungicidal and virustatic activity in vitro and in vivo.

The observational study in question wanted therefore to validate the intuition a potential efficacy of a special and patented ozonated oil, in mixed and low-risk positive HPV, where independently from the presumed effect on the virus, there is a recognized benefit, exploiting the other well-known properties of the product, such as the anti-inflammatory, microbicidal, immunostimulant, regenerating, moisturizing and soothing action of tissues and mucous membranes.

Protocol

Vulvovagi®spray (produced by Erbagil S.r.L) was supplied free of charge to the patients, following the protocol of: 2-3 intravaginal sprays/day for 15 days / night for 2-3 months.

NB: In positive reports for high-risk HPV, colposcopic examination and a biopsy was performed.

Results

In the period between May 2017 and March 2018, about 30 patients were recruited, who due to the required characteristics, were identified as suitable for the use of Vulvovagi®Spray, provided free of charge for the period in question (approximately 5-6 months, maximum period elapsed from the first to the second pap test). 90% of the women treated were negativized. No adverse reactions or side effects have been reported.

Comments

In addition to the already known properties, which were also confirmed in this study, it was possible to observe how Vulvovagi®spray was an excellent routine therapy in low-risk positive HPV women, obtaining 90% negativity of the same at controls. Further studies can demonstrate which mechanisms of action are responsible for this result.

Numerous windows of the investigation remains into the potential of the product, which could be explored in subsequent observational studies in women with different degree of positivity (high grade, mixed), for example, modifying the dosage and / or frequency in applications, or the times themselves treatment, or the simultaneous use of various types of immunostimulants, or specific ones, etc.

At the moment the study encourages to recommend therapy with Vulvovagi® spray in the form of 2-3 sprays/day, for 15 days, for at least two months in those patients diagnosed with ASCUS, CIN-1, CIN-2 or positive low-virulence HPV and low-risk genotypes of cervix carcinoma.

References literature,

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