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International Journal of Current Research
Vol. 8, Issue, 12, pp.44272-44273, December, 2016

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

ISSN: 0975-833X

RESEARCH ARTICLE

SILAUT THERAPY APPLIED TO PATIENTS WITH HPV INFECTION CLINICAL OBSERVATION

***,[1]Angelova, M., [2]Miteva, K., [2]Atanasova, Z., [3]Pecora, T. M. and Kovachev, E.**

[1]Medical Faculty of the Thracian University of Stara Zagora, Department of Obstetrics and Gynecology
[2]Medical Faculty of the Thracian University of Stara Zagora, Department of Health Care
[3]Department of Health Science, Magna Grecia University, Catanzaro, Italy
[4]Medical University "Prof.Dr.Paraskev Stoyanov", Obstetrics Gynaecology Department

ARTICLE INFO

Article History:
Received 26th September, 2016
Received in revised form
22nd October, 2016
Accepted 09th November, 2016
Published online 30th December, 2016

Key words:

Silaut, HPV, Immunostimulator,
Pap test, CIN.

ABSTRACT

Objective: *A medication for the* treatment of microlesions caused by human papillomavirus or due to dryness of the vaginal mucosa. Intended purpose: A protective ointment forming, due to its properties, a protective barrier contributing to the treatment of intraepithelial lesions caused by HPV /papillomavirus/, improving the healing process. Indications: Spectrum of activity with respect to: Lipid coated viruses: Human Papillomavirus, Herpes Simplex virus type 1, Herpes Simplex virus type 2.

Citation: Angelova, M., Miteva, K., Atanasova, Z. and Pecora, T. M. 2016. "Silaut therapy applied to patients with HPV infection clinical observation", *International Journal of Current Research*, 8, (12), 44272-44273.

INTRODUCTION

Doconazol : Proven potency against Aciclovir-resistant herpes viruses. The objective of our observation is to prove the efficiency of this ointment in HPV female patients. These patients were divided in two groups: Group 1 and Group 2. Group 1 included patients with diathermocoagulation of the uterine cervix and 3-month scheme on Silaut. Group 2 was formed by patients without previous treatment of the cervical lesion. An immunostimulator was included in both groups for a period of 3 months. We applied the same preparation to both groups and the patients in these groups were with positive HPV test and Pap tests from II B to III A group. There was no selection according to any signs. The distribution was randomized.

MATERIALS AND METHODS

SILAUT treatment in patients with positive HPV status

52 women were gathered by the end of October, with PAP II A,II B, II C and IIIA and HPV positive status, with or without cervical lesions. Treatment schedule: 3-month therapeutic course combined with the oral administration of an immunostimulant. Referent examinations were held after the 3rd and 6th month, and after 1 year. Assessed parameters: cytological evaluation, colposcopic evaluation, histological evaluation, HPV-testing and after the 6th month from the beginning of the therapy. Up to 80% of the sexually active women are HPV-infected at some point in their lives. ~75% will be infected by oncogenic HPV, type1. The highest rate of infecting is observed during the first 3 years of sexual life. The HPV infection is local and characterized by multiple self-cleaning and re-infecting, due to the lack of any reliable postinfection immunity. This infection can be transmitted also in case of a sexual contact without penetration. Condoms reduce the risk of infection, but cannot totally prevent it. In most cases, the infection is transient and the virus is eliminated by the immune system without causing any harm. However, persistent HPV infections are definitely acknowledged now to be a cause, but not a sufficient factor for the development of cervical cancer. The immune status of a female patient plays a crucial role with respect to the risk of illness. The disappearance of HPV and regression of CIN depends on three factors, namely: the grade of the CIN, the immune status and the HPV features.

This invention also provides for treatment, or contributes to the treatment of current HPV infections of a female individual.

****Corresponding author: Angelova, M.***
Medical Faculty of the Thracian University of Stara Zagora, Department of Obstetrics and Gynecology

Table 1. Group I with electrocautery

Clinical finding	3rd month	6th month	1 year
Completely cured – negative HPV – PAP test IIA	20	20	19
Improvement – IIA group PAP test HPV positive	6	6	7
No improvement – IIB, IIC, IIIA group PAP test – HPV positive	0	0	0
Side effects: bleeding, itching, discomfort	7	2	1

Table 2. Group II without electrocautery

Clinical finding	3rd month	6th month	1 year
Completely cured – negative HPV – PAP test IIA	17	21	24
Improvement – IIA group PAP test HPV positive	19	23	24
No improvement – IIB, IIC, IIIA group PAP test – HPV positive	6	3	2
Side effects: bleeding, itching, discomfort	5	2	1

This medication is used to

- control the zones of cervical & vaginal alterations;
- treat inflammatory and dystrophic alterations and intraepithelial lesions /SIL: squamous intraepithelial lesions/;
- contribute to the reepithelialization process;
- assist the removal of "death cells" and maintain the present lesions clean and, subsequently, promoting their reepithelialization;
- recover the normal physiological environment after any diathermocoagulation or colposcopy;
- treat vaginal and vulvar dryness
- recover of normal physiological environment after a preceding treatment of vulvar condylomas.
- in the cases of lesions causing burning and/or itching: to form form a protective thin film which rapidly reduces the pain, creating faster-healing conditions.

Composition

Curcumin, Docosanol, Emblica officinalis, Aloe vera gel, Polidocanol, Glyceryl laurate, fat acids C12-20 /8/ OE, imidazolidinyl urea, Sodium dehydroacetate, имидазолидинил карбамид, натриев дехидроацетат, CM beta-glucan, disodium EDTA, lactic acid, Vaseline oil, methyl-, ethyl-, propyl-. butyl-, parahydroxibenzoate.

Dosing and mode of application

One application /using a cannula/, during 6 consecutive days, or according to doctor's prescription. After treatment of vulvar condylomas: 2 applications /without cannula/, during 6 consecutive days, or according to doctor's prescription. In the presence of burning or itching: 1 vaginal application /using a cannula/ or on the vulva /without cannula/ per day.

To intraepithelial lesions /SIL/ induced by HPV

First week diagram: 1 vaginal application /using a cannula/ **during six consecutive days.**

Next weeks: 1 vaginal application /using a cannula/, twice a week, during 3-6 months.

PRELIMINARY RESULTS

- PAP regression is the fastest responding factor: immediately after the 3rd month, and only in approx. 4% of the patients it remains unaltered by the 3rd month.
- HPV negativization in 78% of the patient, after the 6th month from the beginning of the therapy.

The above results make evident, that patients whose lesions have been preliminarily treated show relatively faster improvement and healing. Also, the rate of the completely cured patients and those showing improvement is higher in the same group. However, it has been observed that in patients whose lesions have been pretreated, the complaints of bleeding and itching are more frequent compared to the non-pretreated patients in the group. The results have been assessed to be entirely positive, taking into consideration the predominant improvement of the clinical status of the tested patients, as well as the much lower side-effect rate:

- single cases of bleeding only, in the electro coagulation group;
- erythema and itching sensation in both groups.

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