MOSCOW MEDICAL ACADEMY NAMED AFTER I.M. SECHENOV LABORATORY ON STUDIES OF REPARATIVE PROCESSES IN SKIN.

“CONFIRMED”

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REPORT


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REPORT
on clinical approbation of “Herpigen”, carried out in the laboratory of investigation of reparative processes in skin,
Moscow Medical Academy named after I,M, Sechenov

Introduction

In the structure of dermatological diseases the viral ones (herpes simplex, genital, recurrent, zoster) constitute more than 4% and have tendency to increase all over the world. To treat this process a lot of preparations and pharmaceutical agents were suggested either for external or internal use. However the problem of therap of viral diseases of skin remains actual till date. That is why the appearance of new antiviral agent- “Herpigen” is of unquestionable interest.

Characteristics of the investigated preparation.

“Herpigen” is spray, containing extract of radix of licorice on the aqueous base, in which the main active substance is glycyrrhizine acid. The manufacturers of the preparation ( a firm “CATALYSIS” S.L. - Spain) explained, that “Herpigen” is external pharmaceutical agent, indicated for treatment of herpes simplex, including herpes of genital membranes of genitalia and herpes zoster. The preparation is manufactured in vials, 60 ml with the content of glycyrrhizine acid, 0.1 g in 100 ml.

At the recommendation of Pharmacological Committee, Ministry of Health, Russian Federation Dt. 28.10.96 in the laboratory of investigations of reparative processes in skin, Moscow Medical Academy named after I,M, Sechenov the clinical approbation of “Herpigen” preparation in the form of spray was carried out as an external agent for treatment of herpes simplex, genital herpes and herpes zoster.

Approbation was carried out from 15.11.96 to 28.03.97.

Purpose of investigation.

Studies of therapeutic effectiveness of preparation at different forms of herpes, its tolerance and possible side reactions and complications were the purpose of approbation.
Criteria of selection patient for investigation.

We have examined and treated 30 patients (18 women and 12 men at the age of 19 - 57 years old) with clinical evidence of herpes infection on skin and mucous membranes. The main criteria of selection patients for clinical trials of “Herpigen” were evident sign of disease, absence of contradictions for “Herpigen” use, and obligatory agreement of patients.

Besides to investigate the use of “Herpigen” we selected patients who applied to us not later than 48 hours from the moment evidence from literature about action of antiviral preparations in the initial stage of disease.

The treatment was carried out only with “Herpigen”, the use of all other preparations was cancelled.

Clinical characteristics of patients.

All patients were divided into 4 group according to the form of disease in the adopted classification.

In the first group there were 12 patients with initial herpes simplex, clinical evidence was characterized by hyperemia on the skin of face (lips, nasal-labial triangle) and buttocks, edema and itching and later on small grouped vesicular elements. Very often this process was followed by increasing of regional lymphatic glands.

In the second group there were 7 patients with progenital herpes. Clinical evidence was characterized by limited eruptions on skin and genital mucous membranes in the form of grouped vesiculas with serous content, on the hyperemic basis and marked edema of the surrounding tissues. Subjectively the patients suffered from burning, itching and pain in the places of eruptions.

In the third group there were 6 patients with recurrent herpes simplex. The process was localized on skin and mucous membranes of the face, buttocks, genitalias and often it was recurrent (every 2-3 monts) with typical symptoms (hyperemia, edema, grouped small vesiculas, moderate itching). The history of disease was from 11 months to 4 years.
In the forth group there were 5 patients with (varicela) zoster herpes. Four or them had the process on the body (breast, back) and one of them had the process on the face and head, which followed the path of trifacial nerve. In the injured places in the course of nervous trunks there were grouped small papule -vesiculose eruptions, located on the hyperemic basis. Subjectively patinets from moderate itching and pain not only in the places of eruptions but on the way of the whole nervous turnk.

Scheme of treatment and estimation of clinical effectiveness.

“Herpigen” spray was applied on the foci of affection 3 times a day. The course of treatment was from 4 to 10 days depending on character and localization of the process. The dynamic of the course of herpes in the process of treatment with “Herpigen” is shown in the Table 1.

### TABLE 1

Dynamics of release of herpes under the influence of “Herpigen” spray.

<table>
<thead>
<tr>
<th>Groups of patients</th>
<th>Times of the process (days)</th>
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<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Herpes simplex No.12</td>
<td>1</td>
</tr>
<tr>
<td>Progenital herpes No.7</td>
<td>2</td>
</tr>
<tr>
<td>Recurrent herpes No.6</td>
<td>2</td>
</tr>
<tr>
<td>Zoster herpes No.5</td>
<td>1</td>
</tr>
</tbody>
</table>

From the given evidence in Table 1 you can see, that in the course of treatment of herpes simplex in the first 1-2 days from the beginning of disease the action of preparation was revealed within the short period. Almost on the second day of treatment it was noticed a decrease and sometimes a complete disappearance of itching and burning on the skin in the places of eruption, and on the 3-4 days it was a complete disappearance of clinical release of the process.
When applying “Herpigen” spray to the area of eruptions on skin and mucous membranes of genitalias (progenital herpes) at the beginning it was observed disappearance of unpleasant sensations (burning, itching) and on the 4-5 days disappearance of symptoms.

Patients with recurrent herpes were released from clinical symptoms approximately in the same terms as from herpes simplex, that is, on the 3-4 days, but treatment with “Herpigen” didn’t prevent possible sequent recurrent.

In cases of treatment of patients with herpes zoster visible clinical symptoms (hyperemia, eruption) disappeared slower - on the 5-7 days. However, subjective sensations( pain, burning) remained after disappearance of symptoms on skin.

On the basis of clinical supervisions we stated absence of local irritating and allergenic “Herpigen” action on skin and mucous membranes.

Tolerance of the preparation was quite satisfactory.

Analysis of the laboratory investigations (clinical and bio-chemical analysis of blood and urine) being made in the dynamics of treatment in neither case discovered any deviations from norm. That is, “Epigen” didn’t make any side or toxical action on the blood apparatus and function of kidneys.

Comparasion of effectiveness of “Herpigen” spray with local antiviral preparation - “Helipin” ointment, allowed us to establish their equal clinical effectiveness.

Analysis of results of the conducted clinical trials of “Herpigen” in the form of spray at treatment of herpetic infection (herpes simplex, progenital, recurrent and zoster) evidence that preparation obtained strong antiviral potency, particulary if indicated at early stages of disease. In such cases therapeutic effect occurs on the 3-7 days of treatment, depending on the form of disease and localization of process.

CONCLUSION

“Herpigen” (active substance is glycyrrhizine acid) in the form of spray was used for treatment of 30 patinet with various clinical forms of herpetic infection (herpes simplex, progenital, recurrent and zoster).
They were treated only with “Herpigen”.

Herpigen spray was applied on the foci of irritation 3 times a day. The duration of treatment was from 4 to 10 days, depending on character and localization of process. In all cases positive therapeutic effect was achieved, the earlier treatment began the quicker was recovery.

All patients had good tolerance of treatment. Neither side effects of complications were registered. The preparation is convenient from the cosmetic point of view. The observations and investigations which were carried out, evidenced about high antiviral potency of the preparation and its good tolerance.

All the above-mentioned allows us to conclude that “Herpigen” is effective external antiviral agent and can be recommended for registration in Russia and wide clinical use.

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