ABSTRACT

Hypothesis: Approximately 62% of adolescents have been infected with the herpes simplex type-1 (HSV-1) virus. Treatment should always be considered in such patients. HSV-1 can cause a burning sensation or cold sore, and it can spread very quickly to the surrounding skin, causing the formation of blisters. The combination of acyclovir and hydrocortisone cream has been shown to reduce the likelihood of cold sore, and it can also be used to treat the herpes recurrence.

OBJECTIVE

Evaluate the safety of AHC cream for the treatment of herpes labialis recurrences in immunocompetent adolescents aged 12–17 years, following a 5-day treatment with 3-times daily topical administration of AHC cream.

METHODS

Study Design

Singles, open-label, randomized. Phase 3 study conducted at 6 sites in Sweden and 20 sites in Russia between December 2006 and September 2007

Study Treatment

Treatment was subjects-related and consisted of application of AHC cream 5 times daily for 5 days at the first signs or symptoms of a herpes labialis recurrence during the post-recurrence period, preferably prior to the first clinical sign of a cold sore, and before swelling, blistering, or other signs were present.

An overview of the study design is presented in Figure 1. Definitions of stages and categories of HSV recurrences used in the study are presented in Figure 2.

RESULTS

Study Disposition

Of the 204 subjects screened for and included in the study, 120 did not complete the study due to a herpes recurrence and were not treated.

In total, 134 subjects were treated with AHC cream and 12 subjects completed the study. Two subjects discontinued treatment (adverse event, n=1; diabetes, n=1).

Baseline subject demographics and disease characteristics are shown in Table 1.

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Inclusion Criteria

Healthy male or female subjects aged 12–17 years with a history of recurrent HSL with at least 2 recurrences during the past year.

Exclusion Criteria

Recent or recent history of any other viral infection (such as atopic dermatitis, acne, eczema, psoriasis, or chronic vesiculobullous disorders) in the area of herpes recurrences.

History of hypersensitivity or serum sickness to any nucleoside analog antiviral agent, any topical steroid, or to the cream vehicle.

Significant skin conditions (such as atopic dermatitis, acne, eczema, psoriasis, or chronic vesiculobullous disorders) in the area of herpes recurrences.

History of immunosuppressive state.

Non-Ulcerative Recurrence

Non-ulcerative recurrences consisted of vesicular, ulcerative, or hard crust stages.

Ulcerative Recurrence

Ulcerative recurrences consisted of papular, residual swelling, erythema, dry flaking, and ulcer/hard crust stages.

Normal Skin

Normal skin was considered as the start of the study with no lesions.

Study Endpoints

- Adverse events from the start of treatment until the follow-up visit at 3±1 weeks after the last dose of AHC cream was applied.
- Consequences of recurrences as either ulcerative or non-ulcerative.
- Maximum lesion area.
- Erythema.
- Dry flaking and ulcer/hard crust.
- Residual swelling.
- Normal skin.

Conclusions

- Results of the study demonstrate that AHC cream was safe and well tolerated in the treatment of recurrent HSL in adolescents and no safety concerns were identified in the study.
- The benefit of safe and effective treatment of this condition in adolescents and young adults should not be underestimated due to the potential social and psychological consequences.
- Despite the self-resolving characteristic of HSL and subsequent latency, medical treatment for HSL should always be considered.