INTRODUCTION: Most episodes of recurrent herpes labialis are self-limited and mild, but can be troublesome when they occur frequently with painful and unsightly lesions. Therefore, there has been much interest in developing agents that can suppress outbreaks in addition to being therapeutically effective. The objective of the present study was to examine the prophylactic and therapeutic efficacy of 1,5-pentanediol (PD) gel in patients with recurrent episodes of herpes labialis. METHODS: In this placebo-controlled, randomized, double-blind clinical trial, a total of 105 patients with frequent episodes of recurrent herpes were randomized to either PD or placebo. During the 26-week prophylactic phase of the study, the patients applied PD gel or placebo gel twice daily to both lips. Upon recurrence of an episode, a 5-day therapy phase started during which the gel was to be applied eight times daily. After the therapy phase, the patient resumed prophylactic treatment twice daily until the next herpes episode. The main outcome measures were number of herpes episodes during the prophylactic phase of 26 weeks, and successful therapy of occurring herpes episodes with a 5-day treatment. RESULTS: There was no significant difference in recurrence rate between the two groups (P>0.05). During recurrence there was a statistically significant improvement regarding the
therapeutic effect of the symptoms "blistering," "swelling," and "pain" in the PD group. The global evaluation of efficacy by the investigators and patients showed a statistically significant superiority for PD as opposed to placebo ($P<0.001$). CONCLUSION: Under the conditions used in the present study, PD did not show any prophylactic effect against recurrence of herpes episodes. A significantly better therapeutic effect of PD over placebo could be demonstrated on the symptoms "blistering," "swelling," and "pain." PD was very safe as no side effects were observed during the course of the study.