

Light therapy for cold sores

Device name and manufacturer

Virulite™ Cold Sore machine is prescribable on the NHS for treating cold sores (herpes labialis).

A variety of other similar devices are available on the market.

What is the Technology

The devices use 1072-nm narrow-band laser light. The Virulite™ device is approximately the size of an electric shaver which is held against the lesion at the first sign of tingling to deliver light for three minutes, twice a day for 2 days. More frequent application can be used for more severe cases¹. The light is not visible to the naked eye; the device contains an in-built timer to notify the user of the recommended three minute application time.

The manufacturers claim it enhances local immune response and halves cold sore healing time once the blisters have arrived. If used in the tingling stage it can abort a cold sore eruption.

What is the evidence for effectiveness of the device?

Trials with lasers in the treatment of herpes labialis have been conducted over many years. Published clinical studies have generally included small numbers of patients and used differing laser parameters (including differing wavelengths or powers). Despite the differences in trials, a review of the literature found that all trials reported positive results from the use of laser therapy including reduction in the duration of herpetic eruptions and reduced interval between herpes labialis recurrences². No adverse effects were reported in trials.

Three randomised double-blind clinical trials of the narrowband light wavelength used in the Virulite™ device for herpes labialis have been published³⁻⁶. Two have been comparative trials against a sham light device and one has compared it against aciclovir cream in a double dummy randomised trial. In all three trials patients were recruited after advertisements in local media or GP surgeries and therapy was started within 36 hours of a cold sore developing. Trials have involved relatively small numbers of patients.

Two trials randomised a total of 119 patients to a 3-minute treatment of either 1072-nm narrowband light or a sham device three times a day for two days^{3,4}. 1072nm narrowband light is not visible to the naked eye, thus patients were not aware of which device they received. Patients were required to have a history of recurrent herpes labialis (defined as at least three episodes in the previous year). Cold sores affecting only the lips were included in the trials. The primary endpoint in both trials was healing time of the cold sore, defined as the time between the initial presentation and the time when the patient reported re-epithelialisation. The patient-reported time for the cold sore to form a crust was also measured. In one trial, mean healing time with the light device was 6.3 days (SD 3.0) compared with 9.4 days (SD 4.6) for sham device (P = 0.048). In the other trial, median time to healing for the active group was 5.4 days, compared with 7.4 days for the control group, (P = 0.01). In both trials there was no statistically significant difference between the two groups for median time to lesion crusting. No specific side effects from either device were reported.

A further randomised prospective double-blind double-dummy study compared the efficacy of 1072nm narrow waveband light application against topical aciclovir in the treatment of herpes labialis⁵. A total of 60 patients were allocated to one of four groups: a single 5-minute 1072nm narrow waveband light application with or without placebo aciclovir cream or aciclovir cream applied five times daily until the cold sore was cured with or without sham light application. The primary end point was defined as the day that the crust was discarded leaving an uninterrupted underlying skin at the site of the cold sore. Nine patients were lost to follow up and excluded from the analysis, leaving results from 51 patients. No details are available regarding how frequently or for how long patients had suffered from cold sores. Mean cold sore diameter was 2.5-3.3mm. Overall patient-reported healing rates for pooled data were 4.3 +/- 1.8 days (mean +/- SD) with light treatment as compared with 8.5 +/- 3.0 days for aciclovir groups (P < 0.0001). However the majority of patients (71-93%) started treatment between 18-36 hours of onset of symptoms. NICE Clinical Knowledge Service recommends that aciclovir cream be applied at the earliest possible stage, usually when prodromal changes of sensation are felt on the lips and before vesicles appear⁶. The delay in treatment may have affected efficacy of aciclovir. There is no information as to whether it could equally affect efficacy of light therapy. No information of adverse effects was reported.

Costs

The Drug Tariff price for the Virulite™ device (December 2013) is £18.50. The product is currently expected to be deleted from the Drug Tariff from 1st February 2014 although the manufacturers have requested continued inclusion.

The retail price is higher; the manufacturer's website quotes £45 although it can be bought through community pharmacies or other consumer websites from £33.

Other brands of light devices are also available to purchase from approximately £25.

The Virulite™ device is guaranteed for one year¹. The website states that it will deliver unlimited treatment whilst under warranty. The battery is replaceable and each will treat approximately 10-20 cold sores. No other disposables are required.

The Drug Tariff cost of aciclovir cream (5%, 2g) is £1.07 (December 2013). The retail price is approximately £3-£6.

Considerations

Published clinical trials include small numbers of patients. Not all trials included investigator verification of patient-reported outcomes.

There is no trial information of efficacy of repeated use of the Virulite™ device. There are also no published trial data on whether the device can abort a cold sore eruption as claimed on the website.

The majority of patients with herpes labialis will self-treat with over-the-counter purchase of antiviral creams. This can help to minimise the delay before starting treatment. NICE Clinical Knowledge Service notes that the benefits of topical antivirals (aciclovir or penciclovir) are small and require treatment to be initiated at the onset of symptoms before vesicles appear⁶.

The Virulite™ (or similar) devices can be purchased by patients.

References

1. Virulite website (<http://www.vcs.eu.com> Accessed 28/11/13)
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3. G. Hargate A randomised double-blind study comparing the effect of 1072-nm light against placebo for the treatment of herpes labialis Clin Exp Dermatol 2006; 31, 638–641
4. Dougal G, Lee SY Evaluation of the efficacy of low-level light therapy using 1072 nm infrared light for the treatment of herpes simplex labialis. Clin Exp Dermatol 2013; 38: 713-718
5. Dougal G., Kelly P. A pilot study of treatment of herpes labialis with 1072 nm narrow waveband light Clin Exp Dermatol 2001; 26: 149-154
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