



Contact details for more information

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This study has been approved by the NZ Central Health and Disability Committee ref: 18/CEN/151

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**THE EFFECT OF A
NATURAL TOPICAL
TREATMENT ON
COLD SORES**

A team of researchers from the Medical Research Institute of New Zealand and NICM Health Research Institute at Western Sydney University are looking for men and women aged 18 to 65 to join a clinical trial to find out if a topical treatment helps reduce the duration and symptoms of common facial cold sores.



WHY IS THIS STUDY BEING DONE?

Herpes simplex labialis (HSL) – facial cold sores – is a common infection that causes painful sores in and around the mouth. Current topical medical treatments need to be applied regularly to slightly reduce the symptoms and duration of cold sores. This natural topical treatment is a product that could potentially further reduce the severity of symptoms and duration of cold sores with a single application, which will benefit people who suffer recurrent cold sores.

WHY SHOULD I BE PART OF A CLINICAL TRIAL?

By joining a clinical trial, you can help advance scientific knowledge and, in some cases, improve your own health and the health of others with the same condition.

HOW WILL I KNOW IF I'VE RECEIVED A PLACEBO TREATMENT?

Because this is a double-blind, placebo-controlled study, you and the researchers will not know who has received the placebo treatment. This increases the power of the study and strengthens the evidence for the effectiveness of the treatment.



WHO IS ELIGIBLE FOR THE STUDY?

Men and women aged 18 to 65, within 48 hours of initial cold sore symptoms (itching, pain, tingling, numbness, but no blister, ulcer or crust). To ensure you are eligible to join the study, your pharmacist will need to ask you some more questions.

IF I AM ELIGIBLE, WHAT WILL I NEED TO DO?

Briefly, you will need to visit the pharmacy twice, receive just one topical treatment to your cold sore, fill in an online diary each day for 14 days to rate your symptoms, and answer a short survey when you finish.

WHERE WILL THE STUDY TAKE PLACE?

At participating pharmacies and within your own home.

WHAT IF I WANT TO WITHDRAW FROM THE STUDY?

You can withdraw from the study at any time.



HOW MUCH OF MY TIME WILL I NEED TO GIVE?

The first visit will take about 30 minutes, so you can be assessed for eligibility, receive study information, sign a consent form and receive one application of the cold sore treatment in a private consultation area; the daily diary should take about two minutes a day for up to 14 days; your final visit for the healing assessment and filling out the survey should take about 10 minutes; allow five minutes for a follow-up phone call two weeks after your final visit.

WILL I RECEIVE ANY PAYMENT FOR BEING INVOLVED?

Once you have completed your second pharmacy visit, you will be reimbursed \$70 for your study related expenses.

WHAT IF I REQUIRE FURTHER INFORMATION?

Contact the trial Doctor, Alex Semprini (details on the back page) if you would like to discuss the research further or before deciding whether to participate. You can also speak to the pharmacist at the site where you picked up this flyer.

