News
The University of Texas Health Science Center at Dallas
5323 Harry Hines Boulevard Dallas, Texas 75235 (214)688-3404

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CONTACT: Ann Williams
Office: 214/688-3404
Home: 214/375-6043

******Volunteers with genital herpes needed to test new drug

DALLAS--Fifty men and 50 women with genital herpes are needed as research volunteers to test a promising new drug in the Infectious Diseases Unit at The University of Texas Health Science Center at Dallas.

As of now there is no effective treatment known for this disease, which recurs periodically and stays with its victim for life. But a new drug called acyclovir has been shown safe and effective in laboratory animals, and Dr. James Luby, director of the unit in Internal Medicine, has every hope that the drug applied topically (as an ointment) will greatly reduce the healing time. It may even prevent sores from forming.

In a way, acyclovir causes the herpes simplex virus to kill itself. The virus' own enzymes convert the drug to an active form that prevents the virus' replication and kills it. This happens in infected cells, and healthy body cells are apparently unaffected by the medication. "In a way, the virus is fooled into making a compound harmful to itself--sort of a self-destruct system," says Luby.

The herpes simplex virus (HSV) can infect any part of the skin or mucous membrane. HSV Type 1 commonly causes fever blisters on the lips. HSV Type 2, the type under study here, most commonly causes the eruption of painful, itching blisters in the genital area and is passed from person to person usually through sexual contact.

The herpes infection is especially treacherous because it seems to go away. Actually, it only goes into hiding. It has been found that the virus travels up nerve fibers to a group of nerve cells (a ganglion) near the brain or spinal cord, where it stays until something provokes a recurrence of the infection on the skin or mucous membrane, always in the same area.

A recurrence, usually lasting from five to seven days, can be caused by stress, fever or an extreme change in temperature. Sometimes there is no known cause. Herpes victims may have a recurrence as often as every two months. Some may never have a recurrence.

The body's immune system attacks the virus in the skin or mucous membrane but fails to recognize the virus as foreign when it is "hiding" in the nerve cells.

Usually a patient builds up this immunity to the virus, so that recurrences of blisters become less frequent and less severe.

For this study researchers need people who have recurrences at least every two months, says Sandy Butler, the research assistant who handles the skin cultures.

Volunteers should be in general good health and able to come to the medical school for seven visits. Women should be using birth control methods so that they will not become pregnant while the study is going on, says Lisa Near, research nurse.

Volunteers will come in for a first visit when they have a lesion so that it can be cultured for positive identification of the virus. When they are lesion-free, they will come back in and receive a tube of ointment. Half the volunteers will receive a cream containing acyclovir; the other half will get an identical cream with no medication.

(over)

Since this is a random double-blind study, neither the subjects nor the research team will know which volunteer has which cream. This is the way studies of drugs are handled to rule out "placebo effect," that is, patient improvement that quite often happens with a treatment new to the patient because the patient expects it to happen.

The time of application of the ointment is important to this particular study. When volunteers experience a prodrome (a sign that the infection is about to recur, such as a tingling, burning, itching or just an "aura"), they are to apply the ointment. This is to be done before the lesion occurs.

They will then come in for a culture within 24 hours and on certain other days for the next two weeks.

After that, the volunteer's part in the study is complete. Data from this study and studies at other institutions will be analyzed, and if acyclovir's promise holds up, the drug will be approved for use with genital herpes.

What's in it for the volunteers? They don't get paid, but they may hasten the day when there is an effective drug on the market, says Near. Currently there is no accepted treatment. What works for one patient doesn't work for another. "There is probably some placebo effect at work in the various treatments," she says.

If this study shows that acyclovir shortens the episodes of recurrence, and concurrent studies at other medical schools confirm this, it will mean an effective therapy for herpes resulting in less time that victims are contagious. This should result in fewer new cases of the disease now considered an epidemic by public health officials. There are now 300,000 new cases reported in the U.S. each year, and each new patient will host the virus for life.

"If acyclovir can merely reduce the period of recurrences to one or two days, and conceivably this will happen, people will experience pain a shorter time, and they will have less capacity to infect others," says Luby.

The study is funded by Burroughs-Wellcome, the manufacturer of acyclovir. To volunteer as a subject, call 688-3468.

The research team here is also participating in two nation-wide studies of acyclovir for herpes encephalitis and neonatal herpes, funded by the National Institutes of Health.

Herpes encephalitis is caused by a reactivation of the herpesvirus in the temporal lobe of the brain. There are about three cases per year in Dallas.

Parkland Memorial Hospital and Children's Medical Center also see about three cases of neonatal herpes each year. This is a herpes simplex infection in newborn babies who contract the disease from their infected mothers during passage through the birth canal. These cases are usually very serious since the virus attacks the babies' internal organs, and if it reaches the brain, it can result in brain damage or death.

In neonatal herpes, intravenous doses of acyclovir will be tested against Ara-A, a drug that has been effective in some cases.

In herpes encephalitis the study will be similar but will also include tests of Ara-AMP, the more soluble form of Ara-A.

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