

Antiviral Promising in Early HPV Trial

Laird Harrison | March 23, 2015

SAN FRANCISCO — The experimental antiviral drug ranpimase can completely clear away the warts caused by human papillomavirus (HPV), a preliminary study has shown.

If these results are borne out in further studies, ranpimase would be the first drug to attack HPV itself, said Eric Daniels, MD, a research consultant for Tamir Biotechnology in San Diego.

Current treatments can destroy the warts, but the warts can return, he told *Medscape Medical News* here at the American Academy of Dermatology 73rd Annual Meeting.

Although this is the first reported trial of ranpimase for HPV, it has established a reputation for safety over 28 years of study in mesothelioma trials, Dr Daniels said. "We know a bit about ranpimase."

The drug is absorbed by human cells, shuts down RNA synthesis, and prevents viruses from replicating, he explained. "We're allowing the body to take over and catch up."

The drug proved unsuccessful against cancer, but researchers at Tamir Biotechnology are studying its potential against several viral diseases, including Ebola, said Dr Daniels.

In the study, the researchers found that ranpimase inhibited the replication of HPV in cultured human and rabbit cells. They then used a lotion containing ranpimase 1 mg/mL on a human cadaver. More than 75% penetrated into the dermis. The lotion was tested in rabbits and rats and was found to be nonirritating.

The researchers offered the lotion to adults with external genital and perianal HPV warts. They instructed the patients to apply the lotion twice a day. Patients were evaluated once a week for 8 weeks.

Topical Treatment

It is often hard to keep HPV patients in a trial because of their embarrassment about having their genitals and perianal areas examined, Dr Daniels said. Therefore, the investigators were pleased that 13 patients attended at least four of the weekly visits, and eight of these patients attended all eight visits.

At visit 4, four of the patients (30.8%) had no warts, six (46.2%) had a 50% improvement, and three (23.1%) had a 25% improvement.

At week 8, none of the patients who returned for evaluation had any warts. All had achieved a complete remission, Dr Daniels reported.

The only adverse reaction to the medication was irritation, which was experienced by one of the study patients.

On the basis of these promising results, the team at Tamir Biotechnology is planning to start a combined phase 1/2 trial this year, said Dr Daniels.

"One of the things we're interested in is the recurrence rate," he said. "Another is whether we can reduce the viral burden."

In this trial, the researchers used only visual inspection to measure the effects of the drug. In the phase 1/2 trial, they plan to measure the viral load — in samples obtained with cell scraping or cytobrush — with polymerase chain reaction and hybrid captures.

After the presentation, session moderator Joel Gelfand, MD, from the University of Pennsylvania in Philadelphia, asked for details about the adverse reaction.

Another session moderator, Andrew Blauvelt, MD, from the Oregon Medical Research Center in Portland, asked whether before and after photos are available.

Photos were taken for documentation, "but not for broadcast," said Dr Daniels.

Much more research is needed before the drug is established as safe and effective for HPV warts, said Sarah Tuttleton Arron, MD, from the University of California at San Francisco. But she said she will follow the drug's development with interest.

"The existing topical treatments don't specifically target the wart virus," Dr Arron told *Medscape Medical News*. "This is a new mechanism of treatment, and one that could be potentially combined with other treatments for genital warts."

She pointed out that the researchers tested ranpimase against HPV types 6 and 11, but didn't mention any other subtypes. "I would be interested in future studies of this drug against the high-risk cancer-causing HPV types 16 and 18," she said.

Dr Daniels reported that although the team has "tested the drug in several malignant cell lines," none of them have been "specific to variants associated with squamous cell carcinoma."

This study was funded by Tamir Biotechnology. Dr Daniels is a consultant for Tamir Biotechnology. Dr Gelfand reports financial relationships with AbbVie, Amgen, Coherus, Eli Lilly, Elsevier, Endo International, Janssen Pharmaceuticals, Leo Pharma, Merck, Novartis Pharmaceuticals, Pfizer, and Regeneron. Dr Blauvelt reports financial relationships to Amgen, Anacor Pharmaceuticals, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen-Ortho, Merck, Novartis, and Pfizer. Dr Arron reports financial relationships with Allergan, Anacor, Eli Lilly, Genentech, Kythera and Roche.

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