

A Vaccine For Herpes Erupts in the News



By Josh Bloom — March 10, 2016



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Good news in the world of virology.

For the first time, there is a promising vaccine to treat Herpes Simplex Virus type 2 (HSV-2), commonly known as genital herpes. HSV-2 is an infection that infects 500 million people worldwide, and [24 million](#) [2] in the United States, second in prevalence only to HPV among sexually transmitted viruses in the U.S. (The far more common herpes, which causes cold sores, is HSV-1.)

The vaccine, which is called GEN-003 is currently in Phase II trials **(1)**, where it is doing rather well. More on this later.

For being such a common infection, there are big gaps in public knowledge about herpes, so here's a quick primer:

- Herpes never goes away. Rather, the virus retreats to specific nerve roots, where it can be dormant for long periods of time.
- When it re-emerges, it travels up the same nerve root and causes lesions, usually in the same area as before. Stress and changes in immune function are factors in determining re-emergence, but it may occur for no apparent reason.
- Sixty-five percent of people in the U.S. have [antibodies to HSV-1](#) [3]. This means that they have been exposed, but may have never had a cold sore (or they may have and it went away). For HSV-2, that number is [about 15 percent](#) [4].
- Other members in the herpes family include chickenpox (varicella/zoster), cytomegalovirus (CMV), and Epstein-Barr (EBV). Varicella/zoster also hibernates in nerve roots, but when it re-emerges, it does so as shingles. You will not be happy if this happens.

- Both the oral and genital viruses can infect each other's sites, but they do so differently. HSV-1 (oral herpes) causes infection of the genitals much the same as HSV-2, but HSV-2 infection in and around the mouth is relatively unusual, and mild. There is a significant "home court advantage" for HSV-2, but not HSV-1.
- Having one virus does little to protect you from getting the other.

Although HSV vaccines have been extensively studied, clinical trials have consisted of one failure after another, including a [large one](#) ^[5] that bombed in 2012.

There are three drugs for genital herpes that can be used chronically to suppress outbreaks, or short-term to treat them, but they have limitations. Existing antiviral drugs do affect outbreaks, but not shedding (where the virus is active and replicating, though not producing symptoms).

The GEN-003 vaccine helps control both outbreaks and shedding. Outbreaks, as measured by the number of lesions, decreased between 43 and 69 percent, (depending on dose) and viral shedding by 55 percent. Unlike *every other vaccine against infectious pathogens*, GEN-003 is not preventative, it is therapeutic — that is, for people who have already been infected. The researchers are also considering trials to prevent infection, but this will not happen soon.

Zeena Nawas, MD, a research fellow at the Center for Clinical Studies in Houston said, "GEN-003 is a promising vaccine. If it gets approved, it would be the first therapeutic vaccine for genital herpes or any other infectious disease."

Since people are the most contagious during an outbreak or while shedding, the vaccine will unquestionably prevent transmission of the infection. This is especially important for pregnant mothers. Although rare, newborns who are delivered vaginally at a time when the mother is shedding virus can contract the virus and become very ill, and even die. Cesarean-sections are recommended if the mother has her first (primary) outbreak late in pregnancy.

This research is groundbreaking. The first herpes vaccine, as well as the first therapeutic vaccine for an infectious disease. Great work.

Update, 9/22/16

"Astellas, Vical herpes vaccine fails mid-stage study"

The headlines of a failed herpes vaccine are technically correct, but misleading. What failed was a clinical candidate called ASP0113. It was designed to treat cytomegalovirus (CMV), which is a member of the herpes family, but has little in common with HSV1 or HSV2

Note:

(1) In Phase II clinical trials, a drug is evaluated in a few hundred volunteers to see if it works in people. If it does so safely, the next (and final) step is Phase III, where it is tested in many more people.

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Links

[1] <http://www.shutterstock.com/>

[2] <http://www.cdc.gov/std/stats/sti-estimates-fact-sheet-feb-2013.pdf>

[3] <http://www.ncbi.nlm.nih.gov/books/NBK47447/>

[4] <http://www.cdc.gov/std/stats14/other.htm#foot26>

[5] <http://www.nejm.org/doi/full/10.1056/NEJMoa1103151#t=articleBackground>