



What are the potential benefits of joining the study?

If you join this study, you will receive:

- Potential new treatment (or placebo) at no cost to you.
- Study-related medical exams and oversight by a healthcare professional.
- Reimbursement for the cost of out of pocket expenses (e.g. travelling to your study visits).
- An opportunity to contribute to the development of a new treatment for genital herpes.

Where can I get more information about genital herpes?

You may visit the website below or call for more information about genital herpes.



Phone:



Website:

<https://www.sciensano.be/en/health-topics/genital-herpes>

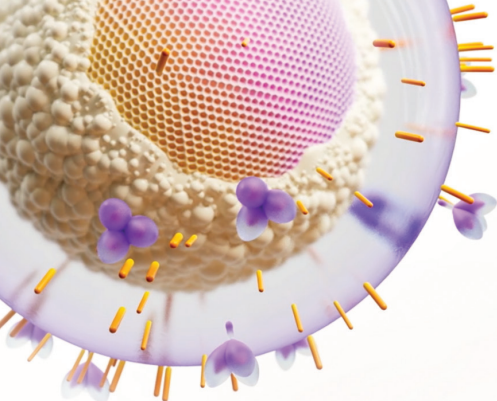
Clinical Trial HSV

**Genital herpes
targeted
immunotherapy
in adults ages
18-60**

Together We Count

[GSK-HSV-TF-EnP]

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What is genital herpes?

Genital herpes is a common sexually transmitted infection caused by the herpes simplex virus (HSV), mainly by HSV-2. Sexual contact is the primary way the virus spreads and can be passed from person to person without being noticed. After the initial infection, the virus lies dormant in your body and can reactivate several times a year. Many people who have genital herpes have no symptoms or have very mild symptoms. Others may have sores appearing as one or more blisters on or around the genitals or rectum. These sores may take a week or more to heal.

Can genital herpes be cured?

There is no cure for genital herpes. However, there are medications that can prevent or shorten outbreaks. These medications can be taken daily and some can make it less likely that you will pass the infection on to your sex partner(s). However, the medications only work while they are being taken.



Why are we doing this study?

The sponsor is currently developing a potential new treatment for genital herpes that could help reduce the frequency, severity and duration of outbreaks. The treatment has not yet been approved in any countries to date. This means that this treatment is only given to people who take part in research studies. This study is being done to test if the treatment is well-tolerated and how well it works. The study aims to understand how it could help to protect against recurrent outbreaks of genital herpes in people already infected with the virus.



Will all participants in this study receive the targeted immunotherapy?

Not all participants will receive the treatment. Some will receive the treatment and others will receive placebo (a dummy vial consisting of a small amount of salt water).



How many people are joining this study?

Approximately 270 people in several countries will take part in this study, which will last for approximately 2 years.



What will be done in the study?

If you join this study:

- You will come to the study site for a maximum of 16 study visits.
- You will receive 2 doses of study treatment or placebo. Neither you nor the study staff will know whether you received the study treatment until after the study ends.
- You will provide blood samples at some visits.
- You will perform self-swabbing at home and return the swabs at your next visit.
- You will complete an electronic diary to record any side effects after the treatment shot, any medications you take, information related to swabbing and any signs or symptoms of genital herpes that you have.



What is required to join this study?

You MAY join this study if you:

- Are between the ages of 18-60 years old.
- Have been diagnosed with genital herpes for at least 1 year.
- Are confirmed to be infected by the HSV-2 virus and test negative for HIV.
- Have had multiple outbreaks in the last year OR before you started suppressive therapy (if applicable).
- Please note other things will need to be checked to help decide if you can join the study.