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Tested at the University Hospitals of Geneva, the Canadian experimental Ebola vaccine is well tolerated by volunteers

Since 10 November, 34 volunteers have already been included in the clinical trial of the experimental VSV-ZEBOV Ebola vaccine at the University Hospitals of Geneva (HUG), at the request of the World Health Organization. After his or her injection, each volunteer was kept under observation for 1.5 hours at the Clinical Trials Unit. To date, no major side effects have been observed after the injections, which triggered the expected inflammatory responses. They have been weak to moderate, with limited cases of mild fever.

Since Swissmedic's approval of the trial, 34 volunteers (out of 115 planned) have come 5 times each to the Clinical Trials Unit of the HUG and the Faculty of Medicine of the University of Geneva. The first visit was for information and screening. It also allowed each volunteer to confirm his/her participation, to be interviewed, and to be examined by the medical team which then also took samples of blood and urine. At the second visit, after a brief interview and another blood test, he or she was given an injection in the shoulder of 10 or 50 million vaccine particles, or a placebo. All participants were closely observed for 1.5 hours, and no complications have been recorded.

During the week following the injection, each volunteer recorded eventual symptoms in a diary and returned four times to the Clinical Trials Unit for a check-up (days 1, 2, 3 and 7 after the injection). Each visit took approximately 20 to 30 minutes, the time needed for a short interview and the collection of medical samples. Observations and initial analysis showed that vaccinated volunteers responded with an inflammatory reaction, precisely as expected. These lasted from a few hours to 2 or 3 days, with mild fever in certain cases and no major side effects.

The HUG team will continue to follow the volunteers regularly, 2 weeks, one month and three months after the injection. This will be done by phone for volunteers who are in regions affected by the Ebola outbreak. Six months after the injection, a final visit is scheduled, including a blood test. The purpose of this monitoring process is, first, to ensure that the two tested vaccine doses do not cause any long term side effects and, second, to determine whether the immune response against Ebola virus depends on the received dose.

Up to early 2015, 15 volunteers will enter this clinical trial every week. Trials of VSV-ZEBOV experimental vaccine have also begun in the United States, Canada, Germany and Gabon; similar trials are expected to start soon in Kenya.

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More than 350 persons have volunteered to test this experimental vaccine in Geneva. The HUG would like to sincerely thank all these people for their generous offer. From now on, the HUG are mostly looking for volunteers who will be traveling to areas affected by the Ebola outbreak. These volunteers will not receive a placebo for ethical reasons

Links

- www.vsv-ebola.ch
- photographs and video footage of the progress of this clinical trial are available: www.hug-ge.ch/ebola-vaccine-candidate/medias
- video of the preparation of the VSV-ZEBOV injection doses at the HUG Pharmacy: www.dailymotion.com/video/x29g4hp_preparatifs-pharmacie-hug-pour-le-vaccin-ebola_news

For more information

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