
Geneva, 5 January 2015

The clinical trial of the VSV-ZEBOV experimental vaccine against Ebola is to resume today

Swissmedic and the responsible committees have approved the proposal of the University Hospitals of Geneva (HUG) to resume the clinical trial of VSV-ZEBOV with a lower dose of this vaccine candidate. The second part of this clinical trial will now test a dose of 300,000 vaccine particles, which should be better tolerated by volunteers and will hopefully trigger the production of enough antibodies. Injections will resume today for the last 56 volunteers, and will take place until end of January.

To avoid joint pain caused by inflammation, the second part of the clinical trial at the HUG will now test a dose of 300,000 vaccine particles, instead of 10 or 50 million particles which were used during the first part of the study. Fortunately, the VSV-ZEBOV vaccine candidate seems able to induce the production of antibodies at lower doses than those previously used at the HUG. This change in the clinical trial protocol has been approved by Swissmedic and three relevant ethics and safety committees. Therefore, vaccinations will resume today for the last 56 volunteers, who will receive either a low dose of the vaccine or a placebo, by groups of 15 people each week.

Since 10 November 2014, a total of 59 volunteers – out of 115 planned – have been involved in the clinical trial of the experimental VSV-ZEBOV Ebola vaccine at the HUG. Initial results showed that the vaccination was well tolerated in the hours and days following the injection. But on some volunteers, the HUG study team observed the onset of mild to moderate joint pain 10 to 15 days after receiving the injection. These symptoms quickly disappeared, even without treatment, and not a single volunteer had to miss work or to be hospitalized.

As a precautionary measure, the injections were suspended in order to study this unexpected phenomenon, the priority of a clinical study always being the safety of the volunteers. Additional observations and analyses showed that ten volunteers had experienced joint inflammations – similar to rheumatism – and that these were indeed induced by the vaccination. The onset of joint inflammation after infection or vaccination with a live vaccine is a known phenomenon, which disappears spontaneously without any consequences.

The VSV-ZEBOV Geneva study team is constantly exchanging information with teams conducting similar studies in Canada, Gabon, Germany and the United States. The clinical trial resumes today in Geneva with the hope of identifying an equally effective, but better tolerated, dose of vaccine. Final results are expected in March 2015.