

Long-term antibody persistence prediction for a tick-borne encephalitis vaccine using statistical modeling

Marco Costantini², Andrea Callegaro¹, Jiri Beran^{3,4}, Ilaria Galgani²

¹GSK, Rixensart, Belgium

²GSK, Siena, Italy

³Institute for Postgraduate Medical Education, Prague, Czechia

⁴Vaccination and Travel Medicine Centre, Hradec Králové, Czechia

Background

Vaccination is an effective way to prevent tick-borne encephalitis (TBE) virus infection and is recommended for individuals living in/traveling to highly endemic areas.

GSK's TBE vaccine demonstrated long-term antibody persistence ≥ 10 years (Y) from first booster dose. We present a statistical prediction ≤ 20 Y post-first vaccination.

Materials and methods

The mathematical model used data from a clinical study that assessed the immunogenicity and subsequently the long-term persistence of 3 licensed TBE vaccine schedules (rapid [R], conventional [C], accelerated conventional [AC] and the non-licensed modified conventional) including a first booster dose 1-3Y post-primary vaccination, and from the subsequent extension studies (NCT00387634/NCT01562444) for 1-5/6-10Y.

A statistical model was applied to predict long-term persistence of neutralizing antibody (NT) titers in the R, C and AC groups using the power-law model (PLM) with random intercept and slope and unstructured covariance structure. Individual antibody levels for each participant at each timepoint ≤ 10 Y were input to the PLM.

Results

From 3Y onward, i.e. after booster vaccination, a similar path was observed across groups, confirmed by the non-significant group effect in the mixed model ($p=0.11$), therefore, the PLM was fitted on pooled data (>3 Y) irrespective of the schedule (R, C or AC). The predicted NT titer at 20Y was 210 (95% confidence interval: 12-3675).

Conclusions

The predicted TBE vaccine antibody persistence was considerably above the surrogate marker of protection level ($NT > 10$) ≤ 20 Y post-first vaccination.

Funding

GlaxoSmithKline Biologicals SA