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Five accelerated schedules for the TBE vaccine FSME- Immun® in last-minute travellers: an open-label, single-centre, randomized controlled trial.

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Background: The purpose of this exploratory study was to evaluate different accelerated tick-borne encephalitis (TBE) vaccine schedules for last-minute travellers.

Methods: In a single-centre, open-label trial, 77 TBE-naïve Belgian soldiers were randomized to the following five schedules with FSME-Immun®: group 1 received one intramuscular (IM) dose at day 0 and 14, group 2 two IM doses at day 0, group 3 two intradermal (ID) doses at day 0, group 4 two ID doses at day 0 and 7 each, group 5 two ID doses at day 0 and 14 each. A single-visit booster was given after one year IM (1 dose) or ID (2 doses).

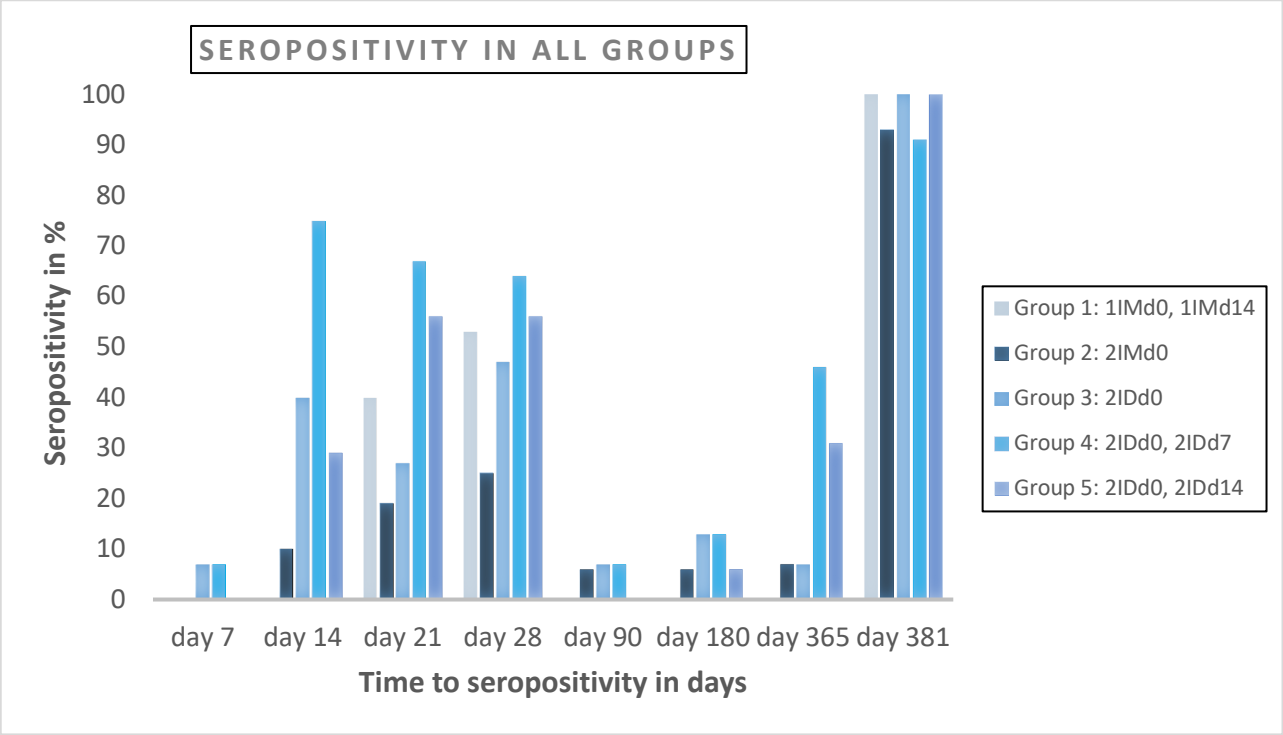
Results: Median age was 19-20 years in each group. Median time-to-seropositivity was shorter in all ID groups compared to IM with group 4 showing the fastest and best response (74.7%, 95% CI 49.4-89.9, day 14). The other schedules peaked lower at day 28. Decline of seropositivity until day 90 was substantial in all groups.

After the booster, all but two non-responders who had a yellow fever vaccination (YFV) in the past, were seropositive. YFV before TBE vaccination was reported in 17% and associated with less TBE-specific antibodies at all time points.

The vaccine was generally well tolerated. Mild to moderate reactions occurred in 100% of ID compared to 13-38% of IM vaccinations after primary immunization.

Conclusion: The investigated accelerated schedules did not confer sufficient protection before the booster vaccination. ID vaccination resulted in faster antibody production than IM but showed more local reactions.

Figure. Seropositivity results in all five vaccine schedules



Legend. Bar chart showing the proportion of seropositivity for all vaccine schedules over time. Group 1 received one intramuscular vaccination at day 0 and day 14, group 2 two intramuscular vaccinations at day 0, group 3 two intradermal vaccinations at day 0, group 4 two intradermal vaccinations at day 0 and day 7 each, and group 5 two intradermal vaccinations at day 0 and day 14 each.