ISRCTN Lay Person Summary for SPL-SPVX02-01 Clinical Trial

ISRCTN Study Title	A study to evaluate the safety and effects on the immune system of a tetanus and diphtheria vaccine which does not need any cold chain distribution or storage
ISRCTN Registration Number	ISRCTN98920861
Clinical Protocol Number	SPL-SPVX02-01
Sponsor	Stablepharma Ltd, UK
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Vaccines are usually kept refrigerated throughout storage and transport. Maintaining this "cold chain" can be expensive and difficult, particularly in remote or low-resource settings, and failures can lead to vaccine wastage. SPVX02 is a new version of an existing tetanus-diphtheria (Td) vaccine that has been reformulated to remain stable at room temperature and to resist damage from freezing.

The purpose of this study was to assess the safety, tolerability and immune response of SPVX02 compared with two licensed Td vaccines, Tetadif® and diTeBooster®..

Sixty healthy adults aged 18 to 55 years from the UK took part. All had received a tetanus-diphtheria vaccination more than 10 years before joining the study. Participants were randomly assigned to receive a single dose of either SPVX02, Tetadif® or diTeBooster®. Participants and most study staff did not know which vaccine had been given. Volunteers were monitored for side effects and provided blood samples before vaccination and on Day 28 after vaccination to assess their immune responses. They were followed up for 28 days after vaccination.

No serious adverse events occurred during the study. Most side effects were mild or moderate and were similar across all three vaccine groups. By 28 days after vaccination, all participants who received SPVX02 had protective antibody levels against both tetanus and diphtheria. The immune responses produced by SPVX02 were similar to those produced by the licensed comparator vaccines.

These results suggest that SPVX02 is safe, well tolerated and produces protective immune responses comparable to existing Td vaccines. If confirmed in larger studies, this room-temperature stable vaccine technology could reduce dependence on refrigerated storage and distribution, helping improve vaccine access and reduce vaccine wastage worldwide.