

A study to evaluate the tolerability and the effects on the immune system of a tetanus and diphtheria vaccine which does not need any cold chain distribution or storage

Submission date 08/05/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 10/07/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 10/07/2026	Condition category Infections and Infestations	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Stablepharma is developing a thermostable lyophilized tetanus and diphtheria (Td) vaccine (SPVX02) based on a reformulation of Tetadif® vaccine. This Phase 2b study will be run in at least 1 site in England and aims to compare the immunogenicity and tolerability of SPVX02 against a comparator vaccine, Tetadif®, using a randomised, single-blind design. The study aims to demonstrate that SPVX02 and Tetadif® generate comparable anti-tetanus and anti-diphtheria post-boost immune responses in healthy adults. The study will be conducted in 160 healthy participants (aged 18-60) who have previously received a primary vaccination against tetanus and diphtheria but who have not received a booster vaccination in the last 10 years. Two cohorts of 80 participants will be randomised 1:1 in a single-blind manner to receive a single vaccination of either SPVX02 or Tetadif®. The primary objective of the study is to compare post-dose antibody titres to obtain immunogenicity data (seroprotection rates). The secondary objectives of the study are to evaluate the tolerability of a single dose of SPVX02 or Tetadif®, and to evaluate additional immunogenicity data (longer term seroprotection rates).

Who can participate?

Healthy volunteers aged 18 - 60 years.

What does the study involve?

Informed consent will be obtained before any study specific procedures are performed. Participants will be screened from Day -42 to Day 0. Eligible participants will attend the clinic to receive a single dose of SPVX02 or Tetadif® on Day 1. On Day 1, an electronic diary, tape measure and thermometer will be provided to perform self-assessments of local and systemic safety and tolerability up to, and including, Day 7. Participants will have a follow-up telephone call on Day 2 (if required at the discretion of the site team based on their eDiary card entries at that time) and will return to the clinic for study assessments on Day 28. End of study visit procedures will be performed at the final clinic visit on Day 28.

What are the possible benefits and risks of participating?

Benefits:

Not provided at time of registration

Risks:

Risks include local and systemic reactions such as pain, redness, swelling at the injection site, fever, fatigue, headache, or more serious reactions (allergic or anaphylactic reactions). To mitigate this, all participants will be closely monitored for at least 30 minutes post vaccination.

Where is the study run from?

Medicines Evaluation Unit (UK)

When is the study starting and how long is it expected to run for?

June 2026 to February 2027.

Who is funding the study?

Stablepharma Ltd (UK)

Who is the main contact?

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Contact information

Type(s)

Scientific, Public

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)

1014057

Sponsor's protocol code number

SPL-SPVX02-02

Study information

Scientific Title

A phase 2b, randomised, single-blind, non-inferiority clinical study to evaluate the immunogenicity and tolerability of SPVX02, a tetanus and diphtheria booster vaccine, against Tetadif® comparator vaccine in healthy adults

Study objectives

Primary objective:

To evaluate the seroprotection rates observed in sera collected from participants on Day 28 post-dose, following administration of a single dose of SPVX02 or Tetadif®

Secondary objectives:

1. To evaluate the tolerability of a single dose of SPVX02 or Tetadif®
2. To evaluate the longer-term seroprotection rates observed in sera collected from participants on Day 28 post-dose, following administration of a single dose of SPVX02 or Tetadif®
3. To evaluate the post vaccination Geometric Mean Titers (GMT) of anti-TT antibodies and anti-DT antibodies observed in sera collected from participants at Day 28 post-dose, following administration of a single dose of SPVX02 or Tetadif®

Ethics approval required

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Ethics approval(s)

Approved 12/06/2026, London - West London & GTAC Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048098; westlondon.rec@hra.nhs.uk), ref: 26/LO/0388

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Prophylaxis

Study type(s)

Efficacy, Safety, Other

Health condition(s) or problem(s) studied

Tetanus and diphtheria preventative vaccination

Interventions

Two treatment groups of 80 participants will be randomised 1:1 using a paper-based randomisation process, in a single-blind manner to receive a single dose of SPVX02 or Tetadif®. Both treatment groups will be dosed in parallel and all participants will be followed up for 28 days post-vaccination.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

SPVX02 [Purified Diphtheria Toxoid PDT for human use, Purified Tetanus Toxoid PTT for human use] , Tetadif® [Purified Diphtheria Toxoid PDT for human use, Purified Tetanus Toxoid PTT for human use]

Primary outcome(s)

Incidence of seroprotection resulting from a single dose of SPVX02 or Tetadif®, seroprotection is defined as an IgG serum antibody titre ≥ 0.1 IU/mL, which is the antibody titre level of anti-TT and anti-DT antibodies that are considered to confer protection against diphtheria and tetanus infection, measured using enzyme linked immunosorbent assays (ELISAs) at 28 days post-dose

Key secondary outcome(s)

1. Incidence of safety and reactogenicity events which include: adverse events, serious adverse events, incidence of local and systemic reactogenicity events observed for 7 days post-dose which include: pain, induration /swelling, tenderness, warmth, erythema at the injection site plus feverishness, chills, myalgia, fatigue, headache, arthralgia and rash
2. Incidence of longer term seroprotection resulting from a single dose of SPVX02 or Tetadif®, longer-term seroprotection is defined as an antibody titre ≥ 1.0 IU/mL, which is the antibody titre level of anti-TT and anti-DT antibodies that are considered to confer longer-term protection against diphtheria and tetanus infection, measured using enzyme linked immunosorbent assays (ELISAs) at 28 days post-dose
3. Evaluation of GMTs of anti-TT and anti-DT antibodies resulting from a single dose of SPVX02 or Tetadif® measured using enzyme linked immunosorbent assays (ELISAs) at 28 days post-dose

Completion date

12/02/2027

Eligibility

Key inclusion criteria

1. Participant is 18-60 years of age at the time of screening with a BMI ≤ 34.9 kg/m²
2. Participant is able to provide informed consent indicating that they are willing to participate and that they understand the purpose of the study and the assessments they are required to undergo as part of their involvement in the study
3. Participant is considered to be in good health with no current conditions that may significantly impair participant safety or influence the study results, as determined by the Investigator
4. Participant does not have any medical condition that causes primary or secondary immunodeficiency
5. Participant has previously received primary and/or booster immunisation with diphtheria and tetanus vaccines, as confirmed by GP records. Alternatively, in the absence of complete vaccination records, the participant has detectable screening tetanus and diphtheria antibody titres of ≥ 0.01 IU/mL
6. Participants who were born female and are of child-bearing potential must be practicing an acceptable, effective method of contraception for the duration of the study. Acceptable methods for this study include:
 - 6.1. Hormonal contraception (use of hormonal contraception should start at least 28 days before the first administration of the study IMP)
 - 6.2. Intrauterine device (IUD)
 - 6.3. Intrauterine hormone-releasing system (IUS)
 - 6.4. Bilateral tubal occlusion/ligation
 - 6.5. Male or female condom with or without spermicide
 - 6.6. Cap, diaphragm or sponge with a vaginal spermicide
 - 6.7. Vasectomised partner (the vasectomised partner should be the sole partner for that volunteer and have received a medical assessment of surgical success)
 - 6.8. Sexual abstinence (sexual abstinence is considered an effective method only if defined as refraining from heterosexual intercourse from signing the icf until the end of the study)
7. Participants who were born female and are not of child-bearing potential must be:
 - 7.1. Postmenopausal: amenorrhea (no menstrual periods) for at least 12 months without an alternative medical cause
 - 7.2. Permanently sterile: permanent sterilization methods include hysterectomy (removal of the womb), bilateral salpingectomy (surgical removal of the fallopian tubes), and bilateral oophorectomy (surgical removal of both ovaries).
8. Male participants must be willing to use a contraception method upon enrolment, during the course of the study, and for 1-month post-dose

Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Serious and uncontrolled chronic disease (i.e., cardiac, pulmonary, renal, neurologic, metabolic, rheumatologic, etc.)
2. Known or suspected autoimmune disease or impairment of immunological function of any cause. Immune-mediated conditions that are stable and well-controlled (e.g., Hashimoto thyroiditis) as well as those that do not require systemic immunosuppressants (e.g., asthma, psoriasis, or vitiligo) may be permitted at the discretion of the Investigator and following discussion with the Medical Monitor. In participants with stable, treated hypothyroidism, mildly abnormal thyroid function tests may not be clinically significant and may be accepted at the discretion of the Investigator
3. Acute medical illness, with or without fever, or an oral or tympanic temperature $>38^{\circ}\text{C}$ within the 72 hours prior to dosing
4. Administration of immunoglobulin or other blood products within the last three months prior to screening; administration of corticosteroids (injected or oral) or other immunomodulatory therapy within 42 days prior to Day 1
5. A positive test result at screening for HIV, hepatitis C virus or hepatitis B virus. HIV-positive participants on antiretroviral therapy with CD4 count ≥ 500 cells/mm³ and HIV RNA ≤ 500 copies/mL within the past 365 days, are permitted at the discretion of the Investigator. Hepatitis C or Hepatitis B infection, if well controlled on stable therapy, with normal liver function and no evidence of immunosuppression, may be permitted at the discretion of the Investigator and following discussion with the Medical Monitor
7. History of allergic disease or any suspected or known hypersensitivity to any of the SPVX02 or Tetadif components
8. Any history of anaphylaxis in reaction to a vaccination
9. Unable to attend scheduled visits or unable to comply with the study procedures
10. Enrolled in another interventional clinical study or has received an investigational intervention in the last 6 months, or within 5 half-lives, whichever is longer
11. Any condition that would pose a health risk to the participant or interfere with the evaluation of either vaccine in the opinion of the Investigator
12. Female and of childbearing potential who does not agree either to remain abstinent or to use effective birth control during the period of the study
13. Intending to become pregnant or breast feeding during the period of the study
14. A history of Guillain-Barré syndrome
15. Receipt of a tetanus or diphtheria vaccination within the 10 years prior to enrolment, as determined from medical review of GP records
16. A previous history of diphtheria or tetanus disease within the last 25 years
17. History of Arthus-type hypersensitivity reaction
18. History of alcohol or substance abuse within the last 5 years. Participants with a positive DOA result at screening may be included at the discretion of the Investigator only if the result is attributable to prescribed or over-the-counter medication or other legitimate use, and there is no evidence of substance abuse or dependency. All decisions must be justified and documented
19. Unable to fulfil all the requirements of the study in the opinion of the Investigator
20. Significant psychiatric history in the last 2 years
21. Presence of permanent body art on both right and left upper arms that would obstruct the ability to observe local reactions at the injection site
22. Any other finding that, in the opinion of the Investigator or Sponsor, deems the subject unsuitable for the study

Date of first enrolment

25/08/2026

Date of final enrolment

12/01/2027

Locations

Countries of recruitment

United Kingdom

Study participating centre**Medicines Evaluation Unit Limited**

The Langley Building

Southmoor Road

Wythenshawe

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England

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Sponsor information

Organisation

Stablepharma Ltd

Funder(s)

Funder type**Funder Name**

Stablepharma Ltd

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available