ISRCTN98920861 https://doi.org/10.1186/ISRCTN98920861

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

Submission date
25/12/2024

Recruitment status
No longer recruiting

Registration date
09/01/2026

Overall study status
Completed

Last Edited
09/01/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 study aims to evaluate the safety, immunogenicity and tolerability of SPVX02 whilst also providing comparative immunogenicity data with Tetadif® and diTeBooster® (comparator investigational medicinal products). The study aims to demonstrate that SPVX02, Tetadif and diTeBooster generate comparable anti-tetanus and anti-diphtheria post-boost immune responses in healthy adults.

Who can participate?
Healthy participants (aged 18-55 years) who have previously received a primary vaccination against tetanus and diphtheria but who have not received a booster vaccination in the last 10 years.

What does the study involve?
Participants will be randomly allocated to receive a single vaccination of either SPVX02, Tetadif or diTeBooster. 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. All participants will have a follow-up telephone call on Day 2 and return to the clinic for study assessments on Days 7 and 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?
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, participants will be closely monitored for at least 30 minutes post-vaccination.

Where is the study run from?
Stablepharma Ltd (UK)

When is the study starting and how long is it expected to run for?
December 2024 to July 2025

Who is funding the study?
Stablepharma Ltd (UK)

Who is the main contact?

Contact information

Type(s)
Scientific

Contact name
Dr Karen O'Hanlon

Contact details
90 Victoria Street
Bristol
United Kingdom
BA1 1HE
+44 (0)7812606184
kohanlon@stablepharma.com

Type(s)
Principal investigator

Contact name
Prof Saul Faust

Contact details
NIHR Southampton Clinical Research Facility
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 (0)238 1204989
s.faust@soton.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
1009178

Protocol serial number
SPL-SPVX02-01

Study information

Scientific Title
A Phase I, randomised, single-blind clinical study to evaluate the safety, immunogenicity and tolerability of SPVX02, a tetanus and diphtheria booster vaccine, against two comparator vaccines in healthy adult participants

Study objectives
Primary objectives:
1. Evaluate the safety of a single vaccination of SPVX02
2. Evaluate the tolerability of a single vaccination of SPVX02, Tetadif® or diTeBooster®

Secondary objectives:
1. To evaluate the seroprotection rates observed in sera collected from participants on Day 28 post-dose, following administration of a single dose of SPVX02, Tetadif® or diTeBooster®
2. 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, Tetadif® or diTeBooster®
3. 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, Tetadif® or diTeBooster®

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/02/2025, London Bridge REC (Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8229, +44 (0)207 104 8140, +44 (0)207 104 8055; londonbridge.rec@hra.nhs.uk), ref: 25/LO/0059

Study design
Single-blind randomized controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Prevention of tetanus and diphtheria infection in healthy volunteers

Interventions
The study will be conducted in 60 healthy participants who have previously received a primary vaccination against tetanus and diphtheria but who have not received a booster vaccination in the last 10 years.
Three treatment groups of 20 participants will be randomised 1:1:1 using a paper-based randomisation process in a single-blind manner to receive a single dose of SPVX02, Tetadif® or diTeBooster®. All treatment groups will be dosed in parallel, and all participants will be followed up for 28 days post-vaccination.

Intervention Type
Biological/Vaccine

Phase
Phase I

Drug/device/biological/vaccine name(s)
SPVX02 , Tetadif, diTeBooster

Primary outcome(s)
1. Incidence of safety and reactogenicity events, which include adverse events , serious adverse events, and the incidence of local and systemic reactogenicity events observed for 7 days post-dose which include: pain, induration, tenderness, swelling, warmth, erythema at the vaccination site plus feverishness, chills, myalgia, fatigue, headache, arthralgia, rash measured using data collected from electronic Case Report Forms (eCRF) at one time point

Key secondary outcome(s))
1. Incidence of seroprotection resulting from a single dose of SPVX02, Tetadif® or diTeBooster®; 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

2. Evaluation of geometric mean titers (GMTs) of anti-TT and anti-DT antibodies resulting from a single dose of SPVX02, Tetadif® or diTeBooster® measured using enzyme linked immunosorbent assays (ELISAs) at 28 days post-dose

3. Incidence of longer-term seroprotection resulting from a single dose of SPVX02, Tetadif® or diTeBooster®; 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

Completion date
28/09/2025

Eligibility

Key inclusion criteria
1. Participant is 18-55 years of age at the time of screening with a BMI ≤30 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 confirms (via GP records, NHS mobile phone application, or similar) that they have previously received primary or booster immunisation with previous diphtheria and tetanus vaccines
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 vaccine)
6.2. Intrauterine device (IUD)
6.3. Intrauterine hormone-releasing system (IUS)
6.4. Male or female condom with or without spermicide
6.5. Cap, diaphragm or sponge with a vaginal spermicide
6.6. Vasectomised partner (the vasectomised partner should be the sole partner for that volunteer)
6.7. 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 alternative medical cause.
7.2. Permanently sterile: permanent sterilization methods include hysterectomy (removal of the womb), bilateral salpingectomy (surgical removal of the fallopian tubes), bilateral tubal occlusion /ligation procedures, 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 1month post-dose.

Participant type(s)
Patient

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Total final enrolment
60

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
3. Acute medical illness, with or without fever, or an oral or tympanic temperature >38°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

6. Received any vaccine in the 30 days prior to screening or planning to receive a vaccine in the 30 days following administration of the study vaccine
7. History of allergic disease or any suspected or known hypersensitivity to any of the SPVX02, Tetadif® or diTeBooster® 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 participated in an interventional clinical study in the last 6 months prior to Day 1.
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 breastfeeding 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
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.
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
17/02/2025

Date of final enrolment
26/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Southampton Clinical Research Facility
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre

Medicines Evaluation Unit Limited
The Langley Building
Southmoor Road
Wythenshawe
Manchester
England
M23 9QZ

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
England
PO6 3LY

Sponsor information

Organisation
Stablepharma Ltd

Funder(s)

Funder type
Industry

Funder Name
Stablepharma Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date