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Typhoid conjugate vaccine booster study in Nepal

Submission date	Recruitment status	[X] Prospectively registered
13/05/2026	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/06/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/06/2026	Infections and Infestations	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

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Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Comparative study on safety and immunogenicity of homologous versus heterologous prime-boost Typhoid Conjugate Vaccine (TCV) schedules in Nepalese children

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Typhoid fever; evaluation of booster typhoid conjugate vaccination schedules and immunogenicity in children previously vaccinated with typhoid conjugate vaccine.

Interventions
This study is a randomised, observer- and participant-blind, parallel-group comparative study in children in Kathmandu Valley, Nepal, who were previously vaccinated with Vi-CRM197 typhoid conjugate vaccine. Participants will be randomised 1:1 by computer to receive either a

homologous booster (Vi-CRM197) or a heterologous booster (Vi-TT/Typbar-TCV). Follow-up will continue for approximately 18 months and will include immunogenicity blood sampling, safety monitoring, scheduled follow-up visits and passive surveillance for enteric fever outcomes.

Intervention Type
Biological/Vaccine

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Vi polysaccharide-tetanus toxoid conjugate vaccine (Vi-TCV) [Tybar-TCV], Vi polysaccharide conjugated to CRM197 (Vi-CRM197) [TYPHIBEV®]

Primary outcome(s)
1. Anti-Vi IgG and IgA antibody responses measured using laboratory immunoassays (ELISA) to assess anti-Vi IgG and anti-Vi IgA antibody concentrations in plasma samples at Day 28 post-booster vaccination

Key secondary outcome(s)
1. Anti-Vi IgG and IgA antibody responses measured using laboratory immunoassays (ELISA) to assess anti-Vi IgG and anti-Vi IgA antibody concentrations in plasma samples at 6 and 18 months

2. Vaccine safety measured using data collected on the proportion of participants developing all adverse events within the first 7 days post-vaccination, and serious adverse events at 7 days, 28 days and 6 months post booster vaccination

3. The incidence of typhoid and paratyphoid disease in the boosted participants measured using blood culture confirmed cases of typhoid or paratyphoid fever from passive surveillance in participants at throughout the study period

Completion date
30/06/2028

Eligibility

Key inclusion criteria
Children living in Kathmandu Valley, Nepal, who:
1. Previously received a single dose of Vi-CRM197 typhoid conjugate vaccine at 15–20 months of age through the national immunisation programme or catch-up campaign
2. Are at least 4 years post-primary vaccination at enrolment (typically aged 5–6.5 years)
3. Have verifiable documentation of prior vaccination
4. Are in good health on the day of vaccination according to the attending doctor
5. Have a parent/legal guardian willing and able to provide informed consent and support study follow-up
6. Live within the study catchment area

Healthy volunteers allowed
Yes

Age group

Child

Lower age limit
4 Years

Upper age limit
6.5 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unable to provide verifiable documentation of prior Vi-CRM197 vaccination
2. Known allergy to any vaccine component
3. Any medical or social condition that may prevent compliance with study procedures or follow-up
4. Known congenital or acquired immunodeficiency that could affect vaccine responses
5. Planning to move away from the study catchment area during follow-up
6. Temporary exclusion at the time of vaccination due to reported fever within the previous 24 hours or receipt of another vaccination within the previous 48 hours

Date of first enrolment
01/07/2026

Date of final enrolment
31/01/2027

Locations

Countries of recruitment
Nepal

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Andrew Pollard (info@ovg.ox.ac.uk).

IPD sharing plan summary
Available on request