

# A Study to Evaluate Safety, Reactogenicity, and Immunogenicity of the GSK 4-component Strep A Vaccine With Aluminum Hydroxide (Alum) or AS37 in Healthy Young Adults

NCT07085702

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 1
<b>Sponsor</b>	GlaxoSmithKline
<b>Enrollment</b>	108 participants

## Key Eligibility Criteria

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### Inclusion (13)

- Participants, who, in the opinion of the Investigator, can and will comply with the requirements of the protocol (e.g., completion of electronic diaries [eDiaries]), return for follow-up visits).
  - Written or witnessed/thumb-printed informed consent obtained from the participant prior to performance of any study-specific procedure.
  - Healthy participants as established by medical history, clinical examination, and laboratory assessments.
  - Satisfies all screening requirements.
  - Male and female participants between and including 18 and 25 years of age at the time of informed consent.
- ... and 8 more (see full listing online)

### Exclusion (27)

- History of rheumatic fever or rheumatic heart disease during the lifetime of the participant as confirmed during interview with the participant or as documented in medical records.
  - Recent history of pharyngitis in the last four (4) weeks will be excluded. These participants can be rescreened once the recent pharyngitis passes the 4-weeks period. Participants with symptoms of acute pharyngitis at Screening will be tested with a Strep A rapid antigen test. Those with positive results will be excluded.
  - Progressive, unstable, or uncontrolled clinical conditions.
  - History (known or suspected) of any reaction or hypersensitivity likely to be exacerbated by any component of the study interventions.
  - Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination.
- ... and 22 more (see full listing online)

## Locations (2 total)

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GSK Investigational Site, Botany, New South Wales, Australia  
GSK Investigational Site, Camberwell, Victoria, Australia