

Research Trial Assessing the Immunogenicity and Safety of Three Meningococcal B Vaccine Strategies Among Patients With Asplenia.

NCT04166656

Status	RECRUITING
Phase	Phase 3
Sponsor	Assistance Publique - Hôpitaux de Paris
Enrollment	84 participants

Key Eligibility Criteria

Inclusion (7)

- Male or female, ≥ 18 to ≤ 75 years old.
- Asplenic patient (for at least 2 weeks) with Howell Jolly bodies visible on blood film
- Splenectomy confirmed by consultation and/or hospitalization report or the ultrasound if it has been performed during the routine follow-up
- Women of childbearing age must have an effective contraception during the first 9 months of the study.
- Participants must give written consent prior to any trial procedure
- ... and 2 more (see full listing online)

Exclusion (13)

- History of meningococcal vaccination B.
- History of anaphylaxis post vaccination.
- Known allergy to any components (active substances or excipients) of both vaccines.
- Patients who cannot stop antibiotics 3 days before blood collection.
- Participants who have received any another vaccines within 4 weeks prior to immunization or who are planning to receive any vaccine within the first 7 months of the study (except the meningococcal ACWY vaccine, the anti-pneumococcal vaccine, the Haemophilus influenzae type B vaccine, the anti-Covid-19 vaccine), annual influenza vaccination which is permitted 2 weeks before and after each vaccination visit of the study and then allowed at any time during the study follow up).
- ... and 8 more (see full listing online)

Locations (1 total)

I-REIVAC/CIC1417 Cochin Hospital, AP-HP, Paris, France