# Infant Malaria Vaccine Schedule Optimization

NCT06879327

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| **Status** | RECRUITING |
| **Phase** | Phase 2 |
| **Sponsor** | PATH |
| **Enrollment** | 1,200 participants |

## Key Eligibility Criteria

### Inclusion (6)

- Signed informed consent or thumb-printed and witnessed informed consent obtained from the parent/legal guardian of the infant.
- Infants must have been born full-term (at e37 weeks of gestation) and \> 2500 grams at birth.
- Immunization schedule Cohorts 1, 2, and 3: : Male and female infants 42-49 days (inclusive) of age at time of enrollment. For infants in Cohort 1, randomization to receive vaccine dose 1 (Groups 1 and 2 of R21/MM or placebo, respectively) will occur at 42-49 days of age. For infants in Cohort 2, randomization to receive vaccine dose 1 (Groups 3 and 4 of R21/MM or placebo, respectively) will occur at 2 months (56-63 days of age). For infants in Cohort 3, randomization to receive vaccine dose 1 (Groups 5 and 6 of R21/MM or placebo, respectively) will occur at 3 months (84-91 days of age).
- The participant's parent/guardian must be willing to avoid travel, particularly in the 28 days after each study vaccination, must confirm willingness to contact the study team in the event of unexpected/unavoidable travel and, for the safety cohort, must confirm availability for the home visits to be conducted by a field worker to collect solicited AEs over the 7 days (day of vaccination and 6 subsequent days) following each study vaccine.
- The participant's parent/guardian must confirm willingness to bring their child to the study clinic / local health care clinic, and capacity to contact the study team in the event the subject has any illnesses or other health concerns during the study.

... and 1 more (see full listing online)

### Exclusion (12)

- Acute disease at the time of enrolment (acute disease is defined as the presence of a moderate or severe illness with or without fever. All vaccines can be administered to participants with a minor illness such as diarrhea, mild upper respiratory infection, without low-grade febrile illness, i.e. axillary temperature \< 37.5°C).
- Clinically significant pulmonary, cardiovascular, gastrointestinal, endocrine, neurological, skin, hepatic or renal functional abnormality, as determined by medical history, physical examination or laboratory tests which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial.
- At time of enrollment, any infant who has received any dose of the hexavalent/pentavalent vaccines, pneumococcal vaccine, rotavirus vaccine, IPV or has received more than one dose of oral polio virus or more than one dose of hepatitis B vaccine.
- Weight-for-height/length Z score of less than -3 or other clinical signs of malnutrition.
- Infant with major congenital defects.

... and 7 more (see full listing online)

## Locations (2 total)

Institut de Recherche en Science de la Santé (IRSS), Bobo-Dioulasso, Burkina Faso
Groupe de Recherche Action en Santé (GRAS), Ouagadougou, Burkina Faso