falciparum. Epidemiological studies have shown that antibodies against SE36 correlate with lower parasitaemia in Solomon Island residents. In a phase I b trial conducted in Uganda, the BK-SE36 vaccine, SE36 formulated with aluminium hydroxide gel, was found safe and immunogenic. Interestingly, highest levels of IgG anti-SE36 protein associated with protection against severe malaria were found in the youngest Ugandan trial participants.

Objectives To assess the safety and immunogenicity of the BK-SE36 vaccine in a randomised controlled double-blind age de-escalating phase Ib clinical trial in younger (≤5 years) malaria-exposed children living in Burkina Faso.

Methods Healthy participants (108) were included in two age cohorts, one consisting of 54 children aged 25–60 months and the other of 54 children aged 12–24 months. Trial participants received 3 intramuscular or subcutaneous injections of the BK-SE36 vaccine at Day 0, Week 4 and 26. Participants allocated to the control group received the control Synflorix vaccine via intramuscular route at Day 0 and Week 26 and saline at Week 4. The participants were followed for one year. Immune responses were evaluated by ELISA, ELISpot and parasite carriage by microscopy and PCR.

Results Preliminary data from an interim analysis (data collected one month after the last immunisation) indicated that the vaccine was safe, well-tolerated and induced an IgG anti-SE36 response in these younger populations. The trial's latest safety, immunogenicity and preliminary efficacy results will be presented.

OC 8552 EFFICACY OF THE CHAD63-MVC ME-TRAP VECTORED MALARIA VACCINE CANDIDATE IN 5–17 MONTHS OLD INFANTS AND CHILDREN IN BURKINA FASO

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10.1136/bmjgh-2019-EDC.31

Background Heterologous prime-boost immunisation with chimpanzee adenovirus 63 (ChAd63) and Modified Vaccinia Virus Ankara (MVA)-vectored vaccines is a strategy previously shown to provide substantial protective efficacy against *P. falciparum* infection in a UK adult phase IIa sporozoite challenge study, and in a trial in Kenyan adults.

Methods We conducted the first phase IIb clinical trial assessing the safety, immunogenicity and efficacy of ChAd63-MVA ME-TRAP in 700 healthy malaria exposed children aged 5–17 months in a highly malaria-endemic area of Burkina Faso.

Participants were randomly assigned to received either ChAd63 ME-TRAP followed eight weeks later by MVA ME-TRAP or 2 doses of rabies vaccine. Monitoring of solicited adverse events was performed for seven days after each vaccination. Unsolicited adverse events were recorded until one month post each vaccination. Serious adverse events and malaria episodes were monitored throughout the study duration. Blood samples were collected at predefined timepoints to assess vaccine immunogenicity.

Results ChAd63-MVA ME-TRAP was shown to be safe and immunogenic, inducing high-level T cell responses [median 326 SFU/106 PBMC (95% CI 290–387)]. However, non-significant low efficacy was observed against clinical malaria during the follow-up period, with efficacy against primary endpoint estimated by proportional analysis being 10.7% (95% CI: −44.2 to 44.7%) at sixth months post MVA ME-TRAP and 3.1% (95% CI −15.0 to 18.3; p=0.72) by cox regression.

Conclusion This study has confirmed ChAd63-MVA ME-TRAP is a safe and highly immunogenic vaccine regimen in children and infants with prior exposure to malaria. No significant protective efficacy was observed in this highly endemic context.

OC 8561 RAPAED TB: AN INNOVATIVE CHILD TB DIAGNOSTIC VALIDATION STUDY

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10.1136/bmjgh-2019-EDC.32

Background Children account for an estimated 1 million new cases of TB every year, representing roughly 7% of the total disease burden. Every year, around 2 09 000 children die from TB, half of those cases are in Africa. The main issue continues to be timely and accurate diagnosis, as treatment outcomes – even in the case of drug resistance – are significantly better than in adults.

Clinical diagnosis in the absence of laboratory confirmation is hampered by non-specificity of symptoms. Diagnostics validation studies in children are difficult – in most studies, very few of the symptomatic children achieved microbiological disease confirmation, resulting in imprecise estimates for test sensitivity.

Design/methods With the RaPaed TB study funded by EDCTP, we are preparing an improved diagnostic validation study design to improve on the traditional approach of a single-gate, double diagnostic study in the target population. The project will evaluate multiple new tests on the same patients, to determine algorithms of screening and confirmatory tests. Most novel tests in this study use non-sputum samples and are therefore more suitable for children.

Allocation of patients to standardised groups will follow the recommendations of the NIH-convened consensus panel on case definitions of paediatric TB diagnostic studies. Using an endpoint review committee will allow blinded review of those new-positive cases, plus matched controls, and determine their likelihood of disease based on clinical data including follow-up, and X-ray. This will improve the quality of evaluation of false positive vs. true positive results of new tests and therefore improve the assessment of specificity.

To improve on sensitivity assessment, the study includes partners with a high number of confirmed cases in past studies and plans to draw in cases of confirmed disease from other diagnostic facilities.

Conclusion This improved methodology will lead to more meaningful and applicable results of diagnostic validation studies.

BMJ Glob Health: first published as 10.1136/bmjgh-2019-EDC.32 on 24 April 2019. Downloaded from http://gh.bmj.com/ on April 10, 2024 by guest. Protected by copyright.