Background

Heterologous prime boost immunization 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 studies, and in a trial in Kenyan adults.

Methods

We conducted the first Phase IIb clinical trials assessing the safety, immunogenicity and efficacy of ChAd63-MVA ME-TRAP in 700 healthy malaria exposed children aged 5-17 months in a highly endemic malaria transmission 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 estimate 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.

Conclusions
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.