Statistical Power Determination for a Cluster-Randomised Malaria Vaccine Trial in a High-Transmission Region of Western Kenya

O, m, o, n, d, i, A, c, h, i, e, n, g, ,, W, a, n, j, i, k, u, M, w, a, n, g, i

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Abstract

Cluster-randomised trials are essential for evaluating interventions such as malaria vaccines in endemic areas. Robust power calculations are required for these trials in high-transmission settings, where local transmission dynamics and clustering effects complicate design. This study aimed to determine the statistical power for a proposed phase III cluster-randomised trial of a novel malaria vaccine in a high-transmission region of western Kenya. The primary objective was to calculate the necessary number of clusters and sample size to detect a clinically meaningful reduction in malaria incidence with sufficient power. A simulation-based approach was employed, using historical malaria incidence data from the region. Input parameters included baseline incidence, intra-cluster correlation coefficient (ICC), expected vaccine efficacy, cluster size, and attrition rates. Power was calculated for different numbers of clusters and follow-up durations, assuming a two-sided significance level of 0.05 and a target power of 80%. The analysis indicated that to achieve 80% power for detecting a 30% reduction in malaria incidence, a design with 40 clusters (20 per arm) and approximately 75 children per cluster would be required. Power was highly sensitive to the ICC; an increase from 0.01 to 0.03 necessitated an additional 12 clusters to maintain power. Adequate power for the proposed trial is achievable with a carefully designed cluster-randomised approach. The required resources are substantial and are

highly dependent on the degree of within-cluster correlation. Future trial designs in similar high-transmission settings should prioritise accurate, local estimation of the ICC during pilot phases. Investigators should consider adaptive designs or increased cluster numbers to mitigate the risk of underestimating clustering effects. statistical power, sample size determination, cluster-randomised trial, malaria vaccine, intra-cluster correlation, Kenya, high-transmission setting This work provides a methodological framework for power calculation in cluster-randomised malaria vaccine trials, highlighting critical parameters for researchers and policymakers planning similar studies in high-transmission African contexts.