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MULTICLADE HIV 1 DNA VACCINE TESTING IN UGANDA: CHALLENGES TO ENROLLMENT

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Makerere University-Walter Reed Project is conducting a phase I vaccine trial to evaluate the safety and immunogenicity of a multiclade HIV I DNA vaccine in 30 HIV uninfected healthy adult Ugandan volunteers aged 18-40.

Eligibility is established by clinical and laboratory evaluation during 2 screening visits which are at least 15 days apart. Volunteers received treatment for intestinal parasites and intercurrent infections if indicated.

A total of 222 volunteers, 63.5% males and 36.5% females, were screened over a period of four and a half months. HIV prevalence was 12.1 %. 145 volunteers were excluded for the following reasons: medical conditions (8.3%), abnormal laboratory values (57.9%), HIV infection (18.6%), other reasons including not turning up for further screening (15.1%). The disqualifying lab values were eosinophilia (41%), neutropenia (21.8%), Eosinophilia and neutropenia (9%), neutropenia and Leucopenia (9%) and other abnormalities (19.2%). Among the 57 (25.6% of screened volunteers) who were eligible to participate, 18 withdrew consent or did not return for initial vaccination.

The biggest challenge to enrollment in the trial was laboratory abnormalities. For future trials, it is important to establish normal laboratory reference ranges in the Ugandan population. The local reference ranges will enable vaccine researchers to set inclusion criteria that are not too restrictive and accurately assess adverse reactions observed during the trial.

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Theme

Enrollment

Suggested topics

1st choice Factors affecting trial enrolment and retention.

2nd choice Issues in prophylactic vaccine clinic trials-Clinical trial results

