

CLINICAL TRIALS IN CLINICALTRIALS.GOV

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Clinical Trials	Malaria Vaccine Trials	Malaria Drug Trials
Total	13	42
Total in Africa	5	31
Phase I	6	3
Phase I/II	5	2
Phase II	2	9
Phase II/III	0	3
Phase III	0	11
Phase IV	0	7
Phase Unspecified	0	7

Table 1. All ongoing clinical trials listed in clinicaltrials.gov with "malaria" as a search term.

Introduction

The clinical trials data in this section are all listed on clinicaltrials.gov. All ongoing clinical trials registered with the US government Department of Health and Human Services and their information posted on the clinical trials.gov website are listed in this article.

Selected summaries of ongoing clinical trials.

CHLORPROGUANIL + DAPSONE + ARTESUNATE (CDA) VERSUS CHLORPROGUANIL + DAPSONE (LAPDAP) FOR UNCOMPLICATED MALARIA

This Phase III clinical trial (NCT00371735) is sponsored by GlaxoSmithKline (GSK) the aims are to compare the efficacy of a fixed-ratio combination tablet of chlorproguanil+dapsone+artesunate to chlorproguanil+dapsone, and collect supporting safety data. Patients 12 months and above, with a diagnosis of acute, uncomplicated *P. falciparum* malaria are being recruited for this multi-center, double-blind, double-dummy, randomized trial.

This study is enrolling in Burkina Faso, Ghana, Mali, and Nigeria. Contact number 1-877-379-3718.

MALARIA VACCINE IN CHILDREN IN MALI

This study (NCT00341250), being sponsored by the

Drugs Tested in Patients With Malaria	No of Trials
Sulphadoxine+pyrimethamine	10
Artemether+lumefantrine	8
Artesunate+amodiaquine	6
Amodiaquine+sulphadoxine+pyrimethamine	4
Artesunate+sulphadoxine-pyrimethamine	4
IPT-sulphadoxinepyrimethamine	3
Mefloquine	3
Chlorproguanil+dapsone	2
Azithromycin+ chloroquine	2
Sulphadoxine+pyrimethamine+azithromycin	2
Chlorproguanil+dapsone+artesunate	2
Arginine	1
RBx11160	1
Malaria Tropica Nosode D200	1
Rosiglitazone	1
Amodiaquine	1
Quinine sulphate taste-masked pellets	1
Azithromycin+artesunate	1
Methylene blue+artesunate	1
Methylene blue+amodiaquine	1
Lopinavir+ritonavir	1
Intravenous artesunate	1
Primaquine	1
Acetaminophen	1
Artesunate	1
Albendazole+praziquantel	1
Chloroquine+sulfadoxine+pyrimethamine	1
Pyronaridine+artesunate	1
Mefloquine+artesunate	1
Efavirenz	1

Table 1. Ongoing clinical trials. All trials are not specifically testing the effectiveness of malaria medications, some are testing drugs for HIV/AIDS, diabetes or other diseases in humans infected with malaria.

National Institute of Allergy and Infectious Diseases (NIAID), will test an experimental vaccine called AMA1-C1 in children to see if it is safe and if it reduces episodes of malaria parasitemia (parasites in the blood) in children exposed to malaria. Children between 2 and 3 years of age living in Don gu bougou or Bancoumana, Mali, and in good general health may be eligible to enroll in this study. Participants will be randomized to receive 2 injections of either AMA1-C1 or a Haemophilus influenzae type B vaccine called Hiberix®, which is approved for use in Mali.

Contact Louis H. Miller MD at 1-301-435-2177 for further enrollment information.

SAFETY AND EFFICACY OF METHYLENE BLUE COMBINED WITH ARTESUNATE OR AMODIAQUINE FOR MALARIA TREATMENT IN CHILDREN OF BURKINA FASO: A PILOT STUDY

This pilot study (NCT00354380) is assessing the safety of the combination methylene blue (MB)-artesunate (AS) and MB-amodiaquine (AD) in treating malaria among children compared with the safety of an AS-AQ regimen, is sponsored by the University of Heidelberg. Children from 6 to 10 years who have the ability to swallow tablets and are diagnosed with uncomplicated malaria from *P. falciparum*, are eligible to enroll in this randomized, open-label, active-control, parallel-assignment, safety and efficacy study.

Contact Olaf Mueller MD, MPH at 00496221565035 (or email olaf.mueller@urz.uni-heidelberg.de) for additional information.

KILIMANJARO IPTi DRUG OPTIONS TRIAL

This trial (NCT00158574) to identify a drug that could be used safely and effectively for intermittent prevention treatment (IPTi), instead of sulfadoxine+pyrimethamine (SP) in infants, has several sponsors and collaborators. This trial proposes using 4 treatment regimens (placebo, mefloquine, chlorproguanil+dapsone, and SP) in 2 different transmission settings, and will involve 1,280 infants in a high-endemic area and 2,440 infants in a low-endemic area, in Tanzania. This trial will enroll in and around Tanzania, Tanga and Kilimanjaro.

For enrollment information, call Roly Gosling MBChB, MRCP at + 255 748 792833.

ARGININE MALARIA TRIAL: STUDY OF ADJUNCTIVE ARGININE IN FALCIPARUM MALARIA

This study (NCT00147368) will use intravenous (IV) arginine to determine whether it can increase nitric oxide (NO) production and have an effect on NO-dependent physiological measurements. This trial is a treatment, non-randomized, open-label, dose-comparison, parallel assignment, pharmacokinetics-pharmacodynamics study. Adults of 18 to 60 years

with a confirmed diagnosis of *P. falciparum* parasitemia will be eligible to enroll.

This trial is enrolling in Indonesia, Papua. Contact Nick M Anstey MBBS at +61-8-8922 8932 or anstey@menzies.edu.au for further enrollment information.

EFFICACY OF SULPHADOXINE-PYRIMETHAMINE AND ARTEMISININ-CONTAINING COMBINATION THERAPY FOR MALARIA

This trial (NCT00140361) is an ongoing monitoring activity of the efficacy of sulfadoxine-pyrimethamine (SP), which is the current national treatment of choice for uncomplicated malaria in Tanzania, and a combination of SP and artesunate among children < 5 years in rural Tanzania (protocol amendment was submitted in 2004 to allow temporary enrollment of adults). The study uses the following interventions in an open label format: SP, SP plus artesunate, lumefantrine plus artemether, and use of an insecticide-treated bednet during sleep. This study is enrolling subjects in parts of Tanzania.

Contact Peter B. Bloland DVM, MPVM at 770-488-7787 or pbb1@cdc.gov for further information.

By T Ziolek

Vaccines Tested to Prevent Malaria	Number of Clinical Trials
AMA1-C1+alhydrogel malaria vaccine	3
Falciparum malaria protein AS02A adjuvant	2
Falciparum malaria protein+ AS01B adjuvant	1
Ad35, CS	1
RTS,S/AS02D vaccine	2
RTS,S/AS01E vaccine	1
MSP1 42-C1+alhydrogel	1
CPG 7909 adjuvant	2
FP9-PP (FP9 polyprotein)	2
MVA-PP (Modified virus Ankara polyprotein)	2
MVA-CSO vaccine	1
PfCSP DNA (VCL-2510) vaccine	1

Table 2. Ongoing clinical trials testing vaccines to prevent malaria.