Gametocytocidal and Transmission-blocking Efficacy of PQ in Combination With AL and TQ in Combination With SPAQ in Mali

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Compare the gametocytocidal and transmission reducing activity of artemether-lumefantrine (AL) with and without a single dose of 0.25mg/kg primaquine (PQ) and sulfadoxine-pyrimethamine with amodiaquine (SPAQ) with and without single dose of 1.66mg/...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23822

Bron
NTR

Verkorte titel
NECTAR3

Aandoening

Malaria

Ondersteuning

Primaire sponsor: London School of Hygiene and Tropical Medicine
Overige ondersteuning: Bill & Melinda Gates Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Change in mosquito infection rate assessed through membrane feeding assays (day 2 and day 7)
Within person percent change (presented as percent reduction) in mosquito infection rate in infectious individuals from baseline (day 0, pre-treatment) to day 2 post treatment in the AL and AL-PQ arms, and day 7 post-treatment in the SPAQ and SPAQ-TQ.

[Time Frame: 3 days (days 0, 2 and 7): 7 day span]

Toelichting onderzoek

Achtergrond van het onderzoek

The purpose of this study is to compare the gametocytocidal and transmission reducing activity of artemether-lumefantrine (AL) with and without a single dose of 0.25mg/kg primaquine (PQ) and sulfadoxine-pyrimethamine with amodiaquine (SPAQ) with and without single dose of 1.66mg/kg tafenoquine (TQ). Outcome measures will include infectivity to mosquitoes at 2, 5 and 7 days after treatment, gametocyte density throughout follow-up, and safety measures including haemoglobin density and the frequency of adverse events.

Doel van het onderzoek

Compare the gametocytocidal and transmission reducing activity of artemether-lumefantrine (AL) with and without a single dose of 0.25mg/kg primaquine (PQ) and sulfadoxine-pyrimethamine with amodiaquine (SPAQ) with and without single dose of 1.66mg/kg tafenoquine (TQ).

Onderzoeksopzet

day 0, day 1, day 2, day 5, day 7, day 14, day 21, day 28

Onderzoeksproduct en/of interventie

Artemether-lumefantrine (20/80 mg artemether and 120/480 mg lumefantrine), Primaquine Phosphate (0.25mg/kg), Sulphadoxine-pyrimethamine with amodiaquine (500mg sulfadoxine and 25mg pyrimethamine and 150mg amodiaquine), Tafenoquine (1.66mg/kg)

Contactpersonen

Publiek

Radboud university medical center
Merel Smit

024-3619515

Wetenschappelijk

Radboud university medical center
Merel Smit

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 10 years and ≤ 50 years
- G6PD-normal defined by Carestart rapid diagnostic test or the OSMMR2000 G6PD qualitative test
- Absence of symptomatic falciparum malaria, defined by fever on enrolment
- Presence of P. falciparum gametocytes on thick blood film at a density >16 gametocytes/µL (i.e. ≥ gametocytes recorded in the thick film against 500 white blood cells)
- Absence of other non-P. falciparum species on blood film
- Hemoglobin ≥ 10 g/dL
- Individuals weighing < = 80 kg
- No evidence of acute severe or chronic disease
- Written, informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Women who are pregnant or lactating (tested at baseline). Urine and/or serum pregnancy testing (β-hCG) will be used.
- Detection of a non-P. falciparum species by microscopy
- Previous reaction to study drugs / known allergy to study drugs
- Signs of severe malaria, including hyperparasitemia (defined as asexual parasitemia >

100,000 parasites / µL)
- Signs of acute or chronic illness, including hepatitis
- The use of other medication (except for paracetamol and/or aspirin)
- Use of antimalarial drugs over the past 7 days (as reported by the participant)
- Clinically significant illness (intercurrent illness e.g., pneumonia, pre-existing condition e.g., renal disease, malignancy or conditions that may affect absorption of study medication e.g., severe diarrhea or any signs of malnutrition as defined clinically)
- Signs of hepatic injury (such as nausea and/or abdominal pain associated with jaundice) or known severe liver disease (i.e., decompensated cirrhosis, Child Pugh stage B or C)
- Signs, symptoms or known renal impairment
- Clinically significant abnormal laboratory values as determined by history, physical examination or routine blood chemistries and hematology values (laboratory guideline values for exclusion are hemoglobin < 10 g/dL, platelets < 50,000/µl, White Blood - Cell count (WBC) < 2000/µl, serum creatinine >2.0mg/dL, or ALT or AST more than 3 times the upper limit of normal for age.
- Blood transfusion in the last 90 days.
- Consistent with the long half-life of tafenoquine, effective contraception should be continued for 5 half-lives (3 months) after the end of treatment.
- History of psychiatric disorders

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	08-10-2021
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	08-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9777
Ander register	LSHTM Research Ethics Committee : 26257

Resultaten