Efficacy and safety of chloroquine plus full dose primaquine for the treatment of Plasmodium vivax malaria in Ethiopia,

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Background

The drug resistance to chloroquine is threating in malaria control and elimination efforts. This study assessed the therapeutic efficacy and safety of chloroquine plus 14 days of primaquine on vivax malaria based on parasitological, clinical, and hematological parameters.

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Methods

A single-arm *in vivo* prospective therapeutic efficacy study was conducted to assess the clinical and parasitological response to chloroquine plus 14 days low dose of (0.25 mg/kg/day) primaquine from December 2022 to March 2023 at Hamusit site using the standard WHO protocol. A total of 100 study participants with *Plasmodium vivax* mono-infection who were over 6 months old were enrolled and monitored for adequate clinical and parasitological responses for 42 days.

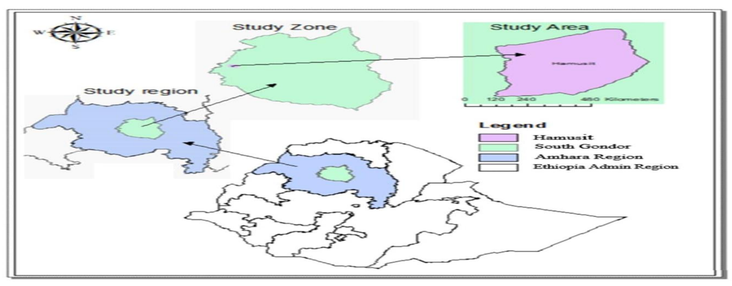

Figure 1 map of study area

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Results

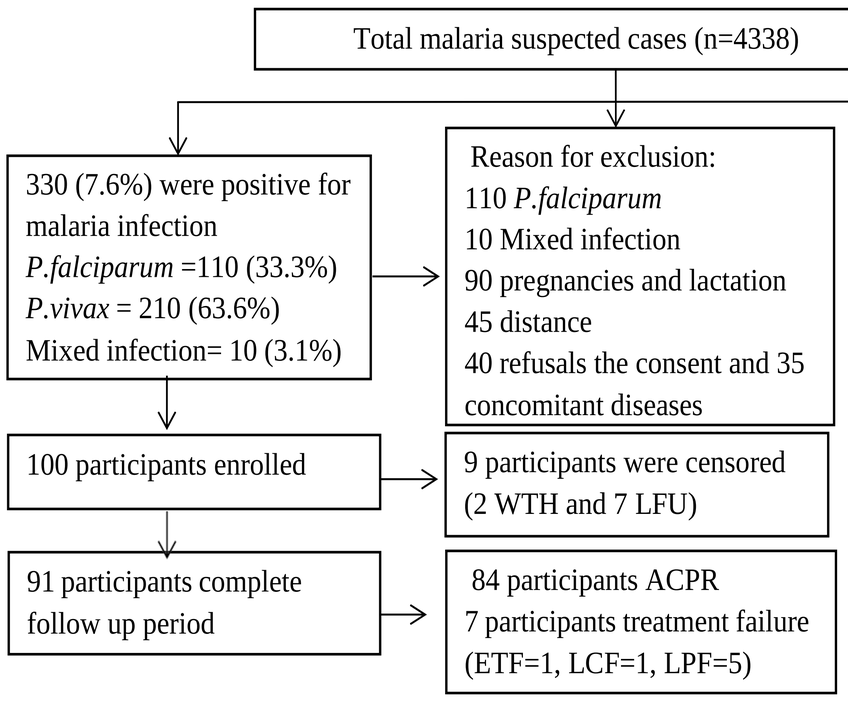

Figure 2 Flow chart of participant's recruitment for 42 days of follow up. Among 210 P.vivax mono infections: 90 pregnancies and lactation, 45 far from the catchment area, 40 refuse the consent and 35 had concomitant disease, so thus individuals were excluded. Nine participants were lost to follow up and withdraw from the study were excluded from the Kaplan Meier analysis. Of 91 study participants 7 were categorized under treatment failure. LFU lost to follow up, WTH withdrawal, ETF early treatment failure, LCF late clinical failure, LPF late parasitological failure, ACPR adequate clinical and parasitological response.

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Data Analysis

A World Health Organization double-entry Excel sheet and SPSS version 25 software were used for the Kaplan-Meier survival analysis and analysis of the data, respectively and also paired t-test was used for analysis of haemoglobine improvements between follow up days.

3

Results cont…

A total of 100 patients were enrolled, 92.6% (95% CI: 85.1%–96.4%) were adequate clinical and parasitological response, and 7.4% (95% CI: 3.6%–14.9%) recurrences were observed among treated patients. The fever and parasite clearance rate on day 3 significantly higher (p=0.033) that was 98% and 94%, respectively. The baseline haemoglobin levels improved significantly compared to those days 14 and 42 (p<0.001). No serious adverse event was observed during the study period.

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Table 6 Hemoglobin recovery

Follow up days	Mean hb (min-max) g/dl	P value
Day 0	11.7 (8.5-18.5)	
Day 14	11.8 (7.9-15.3)	<0.001
Day 28	12.5 (9.5-16.5)	
Day 42	12.7 (8.6-16.9)	

****hb haemoglobine, min minimum, max maximum, gram per deciliter***

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Results cont…

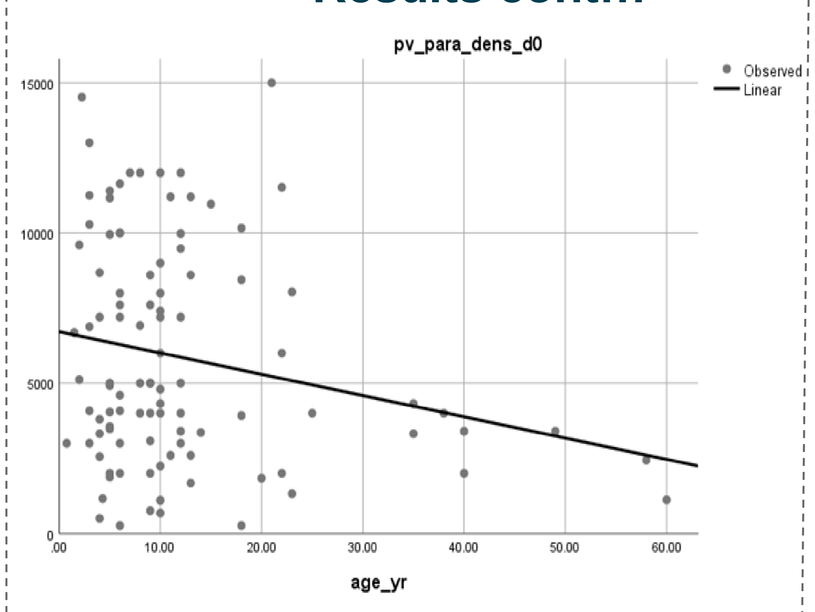

Figure 3 Relation between age and parasite density at baseline of study participants

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Conclusions

The findings of this study revealed that co-administration of chloroquine with Primaquine are efficacious and well-tolerate with fast resolution of fever and high parasites clearance rate. However, further monitoring studies need to determine the efficacy of chloroquine plus radical cure primaquine treatment for *vivax* malaria by direct supervision for the effectiveness of the existing antimalarial drugs and alternative Artemisinin-Based Combination medications.

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Ethics approval and consent to participate

The study ethical clearance was obtained from the Ethical Review Board of the College of Medicine and Health Sciences at Bahir Dar University (IRB) and from institutional review board of the Ethiopian Public Health Institute (EPHI).

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Sample References

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