

<b>Essential</b>	<b>Combination of primaquine with a blood schizontocide known to have high efficacy in the study population,</b> to minimise the risk of recrudescence infections. Primaquine efficacy may vary with partner drug and this must also be confirmed (see Box 3).
	<b>Prolonged duration of follow-up</b> (12 months) – Since relapses can occur over a 12 months period it is important to conduct studies with long duration of follow-up.
	<b>Inclusion of a control arm</b> – The risk and timing of <i>P. vivax</i> relapse varies with the location of the study site, hence the efficacy, safety and risk-benefit of primaquine needs to be gauged where ethically acceptable by comparison with a control arm (given no antirelapse medication).
	<b>Assessment of adverse events with particular attention to haemolysis.</b> Primaquine can cause haemolysis particularly in patients with G6PD deficiency and varies with the study population.
	<b>Multicentre assessment.</b> The risk of relapse varies between <i>P. vivax</i> strains and the intensity of sporozoite inoculation. The risk of hemolysis is related to the G6PD deficiency genotypes prevalent . Both vary regionally. Risk and benefit should be assessed in a range of locations.
<b>Desirable</b>	<b>Retreatment and following patients through multiple recurrences</b> with same treatment regimen. The clinical consequences of relapsing infections and the benefits of their prevention require characterisation of the total number of relapses following an initial infection.
	<b>Quantification of haematological recovery.</b> Both malaria and primaquine result in haemolysis, and thus risk benefit needs to be confirmed through close monitoring of haematological recovery.