

Table legend

Table 1: Definition of early and late treatment failures

Table 2: Study visit schedule

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| Early treatment failure (ETF) | Late treatment failure (LTF) |
|---|--|
| one of the following | |
| 1) Development of danger signs or severe malaria on Days 0-3 with parasitaemia | Late Clinical Failure (LCF): 1) Development of danger signs or severe malaria on any day after Day 3 in the presence of parasitaemia, without having previously met any of the ETF criteria; |
| 2) Presence of parasitaemia on Day 3 with fever (axillary temperature $\geq 37.5^{\circ}\text{C}$) | 2) Presence of parasitaemia and fever on any day after Day 3, without having previously met the ETF criteria. |
| | Late parasitological failure (LPF): Presence of parasitaemia on any day, starting on Day 7, and axillary temperature $<37.5^{\circ}\text{C}$, without previously meeting any of the ETF or LCF criteria. |

Table 2: Study visit schedule

| Day | 0 | 1 | 2 | 3 | 7(± 1) | 14 (± 1) | 21 (± 2) | 28 (± 2) | 35 (± 3) | 42 (± 3) | 49-56 (± 3) | 63 (± 3) | Any other day ¹ | Delivery | 4-6 weeks post-end of pregnancy | 1-year post-end of pregnancy |
|----------------------------------|---|---|---|---|----------------|----------|----------|----------|----------|----------|-------------|----------|----------------------------|----------------|---------------------------------|------------------------------|
| History (symptoms) | X | X | X | X | X | X | X | X | X | X | X | X | X | | | |
| Informed consent | X | | | | | | | | | | | | | | | |
| Examination (clinical) | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | |
| Vital signs | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | |
| Foetal viability | X | | | X | X | X | X | X | X | X | X | X | X | | | |
| Blood Pressure | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | |
| Body Temperature | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | |
| ECG | X | | X | | X ² | | | | | | | | | | | |
| Blood slide ³ | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | |
| Filter paper for genotyping | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | |
| Adverse drug reactions | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | |
| Concomitant medications | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | |
| Haematology | X | | | | X | X | | X | | X | | X | X | X ⁶ | | |
| Treatment administration | X | X | X | | | | | | | | | | | | | |
| Blood sample for PK ⁴ | X | X | X | | X | X | X | X | | X | | | | | | |
| Biochemistry ⁵ | X | X | | | X | | | | | | | | | | | |
| Urine analysis | X | | | | | | | X | | X | | X | | | | |
| Placenta biopsy | | | | | | | | | | | | | | X | | |
| Newborn Assessment | | | | | | | | | | | | | | X ⁸ | X | |
| Newborn LFT | | | | | | | | | | | | | | X ⁷ | | |
| Infant assessment | | | | | | | | | | | | | | | | X |

¹Spontaneous attendance to the health facility (unscheduled visit); ²ECG at Day 7 if abnormal at Day 2; ³Thick and thin blood film; ⁴Four blood samples at scheduled times, first sampling before treatment administration; ⁵In the event of increased LFTs >3xULN, the result will be verified by taking a further sample for analysis as soon as possible (within 24 hours of the original sample). Subsequent blood samples for LFTs will be taken at 48-hour intervals until the results return to ≤2xULN; ⁶Only Hb; ⁷If delivery within or 2 weeks after the active follow up; ⁸Blood sample collected systematically for dried blood spots, blood slide and Hb.