

Supervised versus unsupervised intake of six-dose artemether-lumefantrine for treatment of acute, uncomplicated *Plasmodium falciparum* malaria in Mbarara, Uganda: a randomised trial

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Summary

Background

The six-dose regimen of artemether-lumefantrine is effective and is among combination therapies prioritised to replace antimalarials that no longer work in Africa. However, its effectiveness has not been assessed in the field, and could be compromised by poor adherence, incorrect timing of doses, and insufficient intake of fatty foods with every dose. Our aim, therefore, was to assess the effectiveness of artemether-lumefantrine prescribed under routine outpatient conditions, compared with its efficacy when given under supervision to inpatients with acute uncomplicated falciparum malaria.

Methods

We did a randomised trial to compare the efficacy, safety, and pharmacokinetics of artemether-lumefantrine when given in a supervised (all doses observed with fatty-food intake; n=313) or unsupervised (first dose supervised followed by outpatient treatment with nutritional advice; n=644) setting to patients of all ages (weight >10 kg) with acute, uncomplicated falciparum malaria in Mbarara, Uganda. Our primary endpoint was 28 day, PCR-adjusted, parasitological cure rate. Analysis was by intention to treat and evaluability analysis.

Findings

38 patients were lost to follow-up and one withdrew consent. Day-28 cure rates were 97·7% (296 of 303) and 98·0% (603 of 615) in the supervised and unsupervised groups, respectively. We recorded 15 non-severe, drug-related adverse events, all of which resolved.

Interpretation

Artemether-lumefantrine has a high cure rate irrespective of whether given under supervision with food or under conditions of routine clinic practice. If used as first-line treatment, artemether-lumefantrine could make a substantial contribution to malaria control in Africa, though cost is an issue.