

Introduction

At the start of the COVID-19 pandemic, an herbal medicine Doubase C = *Uvaria brevistipita* + *Haroungana madagascariensis* (DBC) had received authorization for clinical trials in DR Congo. We aimed to determine its efficacy and safety compared to hydroxychloroquine-azithromycin (HCQ-AZI), the national standard treatment for COVID-19 at that time.

Methods

We conducted an open randomized clinical trial between May 2021 and January 2022. Only mild and moderate cases of COVID-19 (WHO classification) were included. Asymptomatic, severe and critical cases were excluded.

Each patient's parameters (NEW score, Ordinal scale, viral load, EKG tracing) were evaluated sequentially and the proportion of changes was compared between the two arms on days 7 and 14.

Results

376 patients randomized (mean age = 40 years, 14 % \geq 60 years, 90.7% mild case, 9.3% moderate case). From day 7, 97.6 % of mild case had a marked improvement in their NEW score and Ordinal scale ($p=ns$). Among patients with moderate case, 5.8% progressed to the severe form of COVID-19 in the HCQ-AZI arm and no patient in the DBC arm ($p=ns$). The viral load was progressively negative (29.8 % negative viral load on day 7 and 86.7 % on day 14) ($p=ns$).

4.4 % of patients on HCQ-AZI experienced QTc interval prolongation and none in the DBC arm ($p=0.021$). We have not recorded any critical cases or deaths.

Conclusions

In both arms, most patients experienced clinical improvement but DBC offers better cardiac safety. The young age of the patients may have influenced the results.