Background and objectives

Since 2011, the French drug agency has sponsored an expanded access program to make MALACEF® (artesunate) available for the treatment of severe malaria. This drug has not yet been approved by European and US pharmaceutical agencies, while it is available in China and several African countries.

The aim of this study was to assess the efficiency and the real-life safety of intravenous artesunate (IA) for the treatment for severe malaria.

Material and methods

- Retrospective, monocentric and observational study
- January 2016 – September 2019
- Pharmacy service computerized system, patients’ records, nominative expanded access authorization forms
- Efficiency: microscopic negativation of the parasitemia
- Safety: monitoring hemoglobin, transaminases, blood platelets, kalemia and creatinemia

Results

Efficiency

Parasitemia negativation after 3 days of treatment

- 3,1 ± 0,7 doses IA
- 67%
- 100% after 7 days
- Return date from infected area: 11 ± 7 days
- Hospitalization date

Safety

- Adverse events
  - Anemia: 36
  - Hyperkalemia: 9
  - Elevation transaminase/thrombocytopenia: 18
  - Creatinemia basal level: 4

- AE general: 0
- AE Anemia hemolysis: 3 post artesunate delayed hemolysis
- Severe: 0

Conclusion and relevance

The intravenous artesunate treatment was effective and well tolerated for all patients. These results seem to be in favour of a broader and an ease of use of the IA.