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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

3,1 ± 0,7 doses IA

Parasitemia negativation after 3 days of treatment

67%

100% after
7 days

Return date from
infected area

Hospitalization
date

11 ± 7 days

Safety

69
patients

Adverse events

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

3

Reports to
Pharmacovigilance

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.



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