

RTS,S/AS01: Adis Evaluation

Clinical Considerations

- First malaria vaccine; targets the pre-erythrocytic stage of *Plasmodium falciparum*
- Shows vaccine efficacy against *P. falciparum* malaria in children; can be used to prevent seasonal malaria
- Vaccine efficacy lower in infants and wanes over time
- Acceptable safety and tolerability profile
- Recommended by WHO; cost effective; provides equitable access to malaria prevention; can be incorporated in routine national immunization programmes

Plain Language Summary

Background and rationale

- Malaria is a life-threatening disease caused by *Plasmodium* parasites, which are spread to humans through bites of infected mosquitoes
- RTS,S/AS01 (Mosquirix®) has EMA's positive opinion for active immunisation of infants and children against *P. falciparum* malaria

Clinical findings

- In phase 3 trials, RTS,S/AS01 showed vaccine efficacy against clinical malaria, severe malaria and malaria hospitalization and was at least as effective as seasonal malaria chemoprevention in children
- RTS,S/AS01 has an acceptable safety and tolerability profile
- Results of the first 2 years of a large scale pilot implementation of RTS,S/AS01 in Africa allowed WHO to revise its malaria vaccine recommendation

Conclusion

WHO recommends RTS,S/AS01 for the prevention of *P. falciparum* malaria in children from 5 months of age living in regions with moderate to high malaria transmission, with an optional use for seasonal malaria

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