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Major clinical trial prompts call for change to treatment guidelines for severe malaria worldwide

6 November 2010

The largest ever clinical trial in patients hospitalised with severe malaria has concluded that the drug artesunate should now be the preferred treatment for the disease in both children and adults everywhere in the world. By treating patients with artesunate rather than quinine, the results show that the number of deaths from severe malaria could be reduced by 22.5 per cent. Part of the work was carried out by researchers at MRC (UK) The Gambia.

An international consortium of researchers, led by Professor Nick White of the Wellcome Trust-Mahidol University-Oxford Tropical Medicine Research Programme in Bangkok, Thailand, compared treatment with artesunate, which is used in Asia to treat severe malaria, against quinine, which has been in use worldwide for over three hundred years. The trial – known as the African Quinine v. Artesunate Malaria Trial (AQUAMAT) – was carried out over a five year period in hospitals across nine African countries and studied 5,425 children with severe malaria. MRC researcher Dr Kalifa Bojang worked as principal investigator for the Royal Victoria Teaching Hospital Banjul and MRC (UK) The Gambia.

Severe malaria kills nearly a million people each year, mainly young children and pregnant women. It is caused by parasites which are injected into the bloodstream by infected mosquitoes. Severe malaria is often the main reason why children are admitted to hospital in Sub-Saharan Africa, and one in ten of these children die.

For over three centuries, doctors have relied upon the bark of a South American tree to treat tropical fevers. This bark gives quinine, a bitter medicine used to flavour tonic water, prevent night cramps, and cure malaria. Quinine is a reliably effective drug, but it is difficult to give by injection and has unpleasant side effects, some of which are potentially dangerous.

AQUAMAT compared quinine against the more recent drug artesunate both given either intravenously or by intramuscular injection, and showed that treatment with artesunate reduced the number of deaths from severe malaria by 22.5 per cent. With artesunate treatment 8.5 per cent of the patients died, compared to 10.9 per cent with quinine. The results were very similar in all the study sites.

Children treated with artesunate were also less likely to slip into a deeper coma or have seizures after the treatment was started. Severe hypoglycaemia – dangerously low blood sugar – was also less common in children treated with artesunate. In addition, artesunate was easy to administer, well tolerated, and proved very safe.

Professor White comments:

"For over a century, quinine administered by injection has been the best treatment available for treating severe malaria, but thanks to the development of the artemisinin compounds, we now have a safer and much more effective treatment. We recommend that artesunate should now

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replace quinine for the treatment of severe malaria in both children and adults everywhere in the world."

Artesunate is derived from a Chinese herb called qinghao (*Artemisia annua*). Nearly forty years ago, Chinese scientists reported that an extract of this herb called was an effective anti-malarial. These reports were treated initially with suspicion but the compounds derived from it (such artemisinin) have steadily gained acceptance throughout the world. In uncomplicated malaria, artemisinin compounds such as artesunate are now part of the artemisinin combination treatments (ACTs) recommended everywhere in the world.

Five years ago the then largest ever trial in patients hospitalized with severe malaria showed that artesunate, given by injection, reduced the death rate compared with quinine. However, this trial was conducted in Asia and most of the patients studied were adults, so there was uncertainty over whether artesunate injection should replace quinine as a treatment of severe malaria in children in Africa, where most of the deaths occur. Today nearly all the children admitted to hospital with severe malaria in Africa still receive quinine.

Dr Arjen Dondorp, Professor White and colleagues from Mahidol University and the University of Oxford, who conducted the original study in Asia, also led the AQUAMAT study. AQUAMAT was carried out in eleven hospitals across Mozambique, Tanzania, Kenya, Uganda, Rwanda, the Democratic Republic of Congo, Nigeria, Ghana, and The Gambia and involved over 200 collaborators. The trial was funded entirely by the Wellcome Trust.

A major factor limiting the use of artesunate has been the lack of availability of a product satisfying international good manufacturing standards. The most widely used product, evaluated in this study, does not yet have this certification but still proved to be superior to quinine.

The trial has been welcomed by Sir Mark Walport, Director of the Wellcome Trust, which supported both the original trial in Asia and the subsequent AQUAMAT study.

> *"This is an extremely important clinical trial of the treatment of malaria, showing improved survival of patients with severe malaria in Africa," says Sir Mark. "There are still many hurdles to overcome and we must be vigilant to protect against resistance to these new drugs and against a market in counterfeit drugs. But Professor White and colleagues have shown that we have the potential to save the lives of hundreds of thousands of children."*

Ends

Notes for editors

1. Dondorp, A. et al. AQUAMAT: an open randomised comparison of artesunate versus quinine in the treatment of severe falciparum malaria in African children. Lancet; e-pub 6 Nov 2010

2. For almost 100 years the Medical Research Council has improved the health of people in the UK and around the world by supporting the highest quality science. The MRC invests in world-class scientists. It has produced 29 Nobel Prize winners and sustains a flourishing environment for internationally recognised research. The MRC focuses on making an impact and provides the financial muscle and scientific expertise behind medical breakthroughs, including the first antibiotic penicillin, the structure of DNA and the lethal link between smoking and cancer. Today MRC funded scientists tackle research into the major health challenges of the 21st century. www.mrc.ac.uk