

Clinical trial recommends new antibiotic for treating typhoid in low income countries

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A large clinical trial comparing treatments for typhoid has recommended the use of gatifloxacin, a new generation and affordable antibiotic. The results of the trial in Kathmandu, Nepal, funded by the Wellcome Trust and the Li Ka Shing Foundation, are published today in the *Lancet Infectious Diseases*.

Typhoid – also known as 'enteric fever' – is characterised by a high fever and diarrhoea. It is transmitted through the ingestion of food or drink contaminated by the faeces or urine of infected people. It causes an estimated 26 million infections each year and over 200,000 deaths and the number of cases is particularly high in parts of South Asia.

The standard treatment for enteric fever since the 1950s was the drug chloramphenicol. The spread of multi-drug resistant forms of the *Salmonella typhi* and *Salmonella paratyphi* bacteria which cause the disease saw a move towards a new generation of antibiotics known as fluoroquinolones, but now there is evidence that the bacteria are becoming resistant to even these drugs.

Gatifloxacin – a new type of fluoroquinolone – was released in North America in 1999 under the brand name Tequin by the pharmaceutical company Bristol-Myers Squibb, but was subsequently withdrawn following the publication in 2006 of a retrospective Canadian study in the *New England Journal of Medicine* which claimed that the drug can cause serious side effects including very high and low blood sugars..

In a study published today, researchers from the Wellcome Trust Major Overseas Programme at the Oxford University Clinical Research Unit, Ho Chi Minh City, Vietnam, together with researchers at the Oxford University Clinical Research Unit–Patan Academy of Health Sciences, Kathmandu, Nepal, conducted an open-label, randomised, controlled trial to compare gatifloxacin against chloramphenicol. Their study, which enrolled 844 children and adults, is the largest randomised controlled trial for enteric fever carried out to date.

The researchers found both drugs to be equally effective. They found no difference between the two drugs in terms of treatment failure and the time to clear the fever. However, the side effects, including anorexia, nausea, diarrhoea and dizziness, were significantly worse in patients being treated with chloramphenicol.

An added advantage of gatifloxacin over chloramphenicol is that the former only needs to be taken once a day for seven days and the average cost for this treatment course is US\$1.50. Chloramphenicol, on the other hand, needs to be taken four times a day for fourteen days at an average price for the course of US\$7. Gatifloxacin appears to work despite drug resistance to the older antibiotics (chloramphenicol and older fluoroquinolones) and can therefore be used in settings where the pattern of resistance is not known.

Because of concerns of the side effects of gatifloxacin in an elderly North American population, the researchers closely monitored the patients' blood sugar levels. Although they found a higher number of patients with elevated blood sugar levels during the first week of treatment, these levels had returned to normal once the treatment course had ended and no change in treatment was required.

"Although there have been concerns of the [side effects](#) of gatifloxacin in elderly people from North America, this was amongst a very different

population to those needing the drug in the developing world," says Dr Buddha Basnyat. "Gatifloxacin remains a very effective drug in young people who are not overweight and who have no tendency to diabetes.

"We have very few antibiotics for diseases of the developing world and it is very important that we do not lose the effective ones we have because of adverse events in a different population that we do not see in the population we treat."

The researchers have now submitted evidence to the World Health Organization (WHO) arguing that Gatifloxacin should be retained in young populations not at risk of diabetes. It is understood that the WHO will consider this evidence later this year. The drug is also in Phase III trials for treatment of tuberculosis.

Provided by Wellcome Trust

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