

2,784 vaccinations later

April 29 2011, By Jonathan Wood



Mothers and babies taking part in the trial in South Africa.

The two thousand, seven hundred and eighty-fourth baby has been vaccinated today in South Africa as part of a clinical trial of a new vaccine against tuberculosis. The new TB vaccine is the most advanced in development anywhere in the world.

That's the last baby in the trial, and marks completion of trial enrolment almost two years to the day after the study was first announced.

"We are extremely proud of this achievement and are eager to see the study results, which are expected to be available in 2012," says Dr. Helen McShane, who developed the [vaccine](#) at the Jenner Institute, Oxford University. "This milestone brings us a step closer to potentially having a new [TB vaccine](#), from which millions of people around the world would benefit."

It's certainly quite a milestone, and marks a great deal of work to vaccinate all these babies under 1 year old in an area where there is one of the highest rates of TB in the world.

But why precisely 2,784 babies, not 2,500 or 3,000?

Helen explains that it is entirely down to the calculations used to plan the trial. These sums showed that 2784 babies should give enough statistical weight to be able to see a significant improvement in preventing TB over the 90-year-old (but still standard) BCG jab.

The new vaccine is designed to be given to infants after they have received the BCG vaccine, boosting the immune response further. All the babies in the trial have received the BCG vaccine, with half then getting the trial vaccine and half a placebo. "If successful, the next steps would be to plan a phase III trial and licensure of the vaccine," Helen says.

The current trial was a phase IIb trial, and is the first to be able to really determine whether the vaccine gives infants any protection against TB. A larger phase III trial would pin down exactly the size of any benefit and guide how the vaccine could be rolled out.

The trial in Worcester, about 100km from Cape Town, is being conducted by the University of Cape Town's South African [Tuberculosis Vaccine Initiative \(SATVI\)](#), in partnership with Aeras, the Wellcome Trust, and the Oxford-Emergent Tuberculosis Consortium Ltd (a joint venture between the University of Oxford and Emergent Biosolutions Inc formed to develop the vaccine)

"We are pleased to report that the trial has run smoothly to date," says Dr. Hassan Mahomed, who has led the trial at SATVI.

Provided by Oxford University

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