

## Collaboration leads to new rotavirus vaccine

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A new rotavirus vaccine that has the potential to save over half a million lives worldwide each year has reached a pivotal milestone after clinical trials results found the vaccine provided a strong immune response in over 90 per cent of babies that received a course of the vaccine.

Rotavirus is the most common cause of severe diarrhoea among infants and young children and results in the death of over half a million children under five years of age worldwide each year, mainly in developing countries.

The clinical trial, which was done in collaboration between the University of Otago and the Murdoch Childrens Research Institute at the University of Melbourne, involved 95 babies at Dunedin Hospital receiving a course of three doses of the <u>vaccine</u>, with the first dose given within the first days of birth.

The breakthrough results will be presented at the 11th International Rotavirus Symposium to be held 3-5 September in New Delhi, India.

Lead researcher, Professor Julie Bines of Murdoch Childrens, the University of Melbourne and The Royal Children's Hospital said the results provide confidence that this vaccine will be very effective in preventing severe rotavirus gastroenteritis in very young babies.

"These results are a major step forward for the development of the vaccine as it is the first time a <u>rotavirus vaccine</u> has been given to newborns. Not only have we shown that this <u>novel vaccine</u> is well



tolerated in newborns but it produces a strong immune response in a newborn, suggestive of promoting early protection from severe gastroenteritis," she says.

"The advantage of this vaccine over the currently available vaccines is the birth dose which is the earliest opportunity to provide protection to babies from severe rotavirus gastroenteritis. This world-first approach has enormous potential to reduce disease and dying in the most vulnerable children around the world."

The 'RV3' Rotavirus Vaccine candidate has been developed from a unique strain of rotavirus that was found naturally in healthy asymptomatic newborn babies, who were then protected from severe rotavirus diarrhea in the first two years of life.

University of Otago Senior Clinical Lecturer in Women and Children's Health Dr Pam Jackson says the clinical trial in Dunedin went very well, and she thanks families for their participation, and also the Health Research Council (HRC) of New Zealand, which funded the study.

"Without their willingness to help this would have been difficult to assess, and we are delighted that this vaccine has been shown to be an effective way to prevent this disease."

Newborn babies and infants in Dunedin were given three doses of the <u>oral vaccine</u>, called RV3-BB, or a placebo to ascertain the level of immunity to rotavirus generated by the vaccine. The vaccine is derived from a harmless strain of rotavirus found in newborn babies. In New Zealand, rotavirus is responsible for 1500 hospital admissions of children under five years of age each year.

Although babies in Australia have had the benefit of rotavirus vaccines the new vaccine has a number of advantages -such as the ability to



administer earlier and prevent disease in very young <u>babies</u> that are currently not protected.

The research and development of the 'RV3' vaccine is being led and conducted by academic institutions rather than the pharmaceutical industry with the intention to partner with developing country manufacturers so that the vaccine will ultimately be affordable for developing countries, where they are needed most.

The vaccine is the culmination of over four decades of research in Australia by the Murdoch Childrens Research Institute, The Royal Children's Hospital Melbourne and the University of Melbourne, following the discovery of rotavirus by a team of staff led by Professor Ruth Bishop in 1973.

Clinical trials are also underway in Indonesia. It is hoped the vaccine will be available for widespread use in 2016.

## Provided by University of Otago

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