

## Clinical research on a Japanese Encephalitis (JE) Vaccine is being conducted in Australia

A clinical research study, also known as a clinical trial, is a carefully designed test, to evaluate the safety and effectiveness of an investigational drug or treatment, in a group of volunteers. It measures a drug's ability to treat a condition (or, in this case, to prevent a disease), its safety, and its possible side effects. Investigational means that the Australian Therapeutic Goods Administration (TGA) has not yet approved the drug for the intended use in the population under investigation.

The information obtained from clinical trials helps the TGA, to determine if a drug is safe and effective – a requirement before any drug can be prescribed by doctors and sold in the Australia. Japanese Encephalitis (JE) vaccine clinical trials, such as this one, also help medical professionals learn more about the Japanese Encephalitis (JE) virus and different approaches to preventing Japanese Encephalitis (JE).

Only the study doctor can determine eligibility, but your child may be eligible to volunteer if:

- They are 2 months to 17 years old
- They are in good health
- They have not had a vaccine against JE, yellow fever, dengue, or West Nile virus prior to the study
- They are planning to travel to an area where JE is endemic.
- There is plenty of time before departure to schedule other travel vaccines around the study vaccine.



### About JE

JE is a dangerous infectious disease of the brain caused by a virus that circulates in Asia, mainly affecting children.

The JE virus is spread by mosquitoes in China, India, Japan, Korea, Vietnam, Thailand, the Philippines, Indonesia, and Papua New Guinea, with one case of JE being contracted in Australia. In Asia, there are 30,000 to 50,000 cases reported annually. Not everyone who comes in contact with this virus gets sick, but if they do get sick, JE is fatal in about 30% of sufferers, and about 50% of survivors have permanent brain damage. JE is rare amongst Australian travelers but there have been reported cases.

**If you might like to volunteer for this JE Study, you can find out more information by calling**

**Dr Deb Mills Ph 07 3221 9066**

**Dr Deb The Travel Doctor**

**5/247 Adelaide Street Brisbane**

or

[www.thetraveldoctor.com.au](http://www.thetraveldoctor.com.au)

**and click on link to JEstudy**

Dr Deb Brochure: Version 1 dated 27 January 2009



## Japanese Encephalitis (JE) Study

Researchers in Australia are seeking travellers under 18 years of age who are planning to visit Asia, to volunteer for a research study on a new JE vaccine for children travelling to these risk areas.



## About the study

The purpose of this study is to review the side effects and antibody levels of the study (JE) vaccine in those under 18 years. The study JE vaccine is already approved for use in adults only, in Australia, The United States, Europe and Canada. Participation in this study will require 4-5 doctor visits, 3-4 blood tests, and some phone calls, over the course of about 8 months. Study volunteers do not pay for study-related doctor visits, pathology tests, or the study vaccine. Volunteers will also receive reimbursement for reasonable travel costs to attend their appointments.

As with any clinical research study, volunteers may wish to discuss this with the family, or doctor before deciding to participate.



### The likelihood of contracting JE

In regions where the virus is present, about 3% of mosquitoes carry the JE virus.

Although the great majority of JE virus infections do not make people sick, it is estimated that between 1 in 20 and 1 in 1000 infected persons develop obvious disease. For most travellers to Asia the risk of acquiring JE disease is estimated at 1 in 1 million travellers per month of stay.

The risk for the individual traveller is hard to estimate and depends on factors such as when you go, where you go, how long you stay and what you do while you are there. The risk increases significantly when you travel during the wet season, the longer you stay in rural areas, and the more exposure you have to mosquito attacks, especially between dusk and dawn.

*Japanese Encephalitis (JE) is more dangerous to children than to adults.*

### Symptoms of JE disease

If an infected person does get sick, the symptoms usually start 5 to 15 days after the mosquito attack, with a flu-like illness. In children, stomach and bowel symptoms may be more noticeable at the beginning of the illness. If the infection reaches the brain and spinal chord, the sufferer may develop symptoms of fits, paralysis, loss of speech, and coma, leading to death in about 30% of persons and permanent brain damage in about 50%.

### Other options for JE protection

Australia does not have any licensed paediatric vaccine for JE available to protect your child. Mosquito avoidance measures such as applying repellent, sleeping under bed nets and wearing permethrin treated clothes are recommended whether or not vaccination is given. Adults can receive the Jespect vaccine for JE protection.

