Young Person Information Sheet

Western New South Wales Local Health District

Study Title	**Japanese encephalitis vaccine via intradermal route in children and adults (JEVID-2)**
Principal Investigator/s	**Associate Professor Nicholas Wood** **National Centre for Immunisation Research and Surveillance** **Professor Colleen Lau and Dr Luis Furuya-Kanamori** **University of Queensland**
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1. Introduction

You are invited to participate in a research study titled **Japanese encephalitis vaccine via intradermal route in children and adults (JEVID-2).** This information sheet tells you about the study. It will help you choose if you want to join or not. You can ask your parents, carer, friend or doctor if you need. You do not have to join this study if you do not want to.

Before you think of joining this study, you should know why and how the research is being done. Please read this information sheet carefully.

2. What is the purpose of this study?

Japanese encephalitis (JE) is a rare but serious illness caused by the Japanese encephalitis virus. It is spread to humans by infected mosquitoes. It is spread when a mosquito bites an animal (such as pigs or waterbirds) that has the JE virus and then this mosquito bites a human.

JE virus has now been detected in pigs and humans in Western and Southern NSW, as well as in Queensland, Victoria, the Northern Territory and South Australia. It is possible that we may see some JE cases over summer in Australia.

In most cases JE infection is mild and in others the infection is so mild that people will not even know they have had the infection. However, it can sometimes lead to fever, headache and vomiting. Rarely (less than one percent) it can be more severe and lead to brain infection. There is no treatment for JE viral infection.

There are effective and safe JE virus vaccines which can be given to children over 2 months old to protect against JE infection. It is recommended the vaccine (0.5ml) be given by an injection into the fat area under your skin, called a subcutaneous (SC) injection. Another way to give the vaccine is to give a smaller dose, only 0.1ml, into the skin. This is called an intradermal (ID) injection.

By giving a smaller dose of the vaccine ID, we can vaccinate more people with each dose of vaccine vial. ID administration of other vaccines using smaller doses have been shown to be as effective as SC administration for other viruses, e.g. yellow fever and rabies. ID administration is also used for BCG (protects against tuberculosis) and is now recommended for monkey pox vaccination in adults.

ID JE vaccination has found to be safe and result in strong antibody responses in adults; however, it has not yet been tested in younger children, adolescents and older (>50 years) populations. It is more painful than when the vaccine is given by a subcutaneous injection.

We aim to study the safety and antibody (immune) responses of the JE vaccine when given intradermally in children and adolescents aged >5 years to < 18 years old and also in adults.

The results of this study may result in a change to the way JE vaccine is recommended to be given in Australia and allow more people who are at risk of JE to be vaccinated.

3. Why have I been invited to this study?

You are invited to take part in this study because you are healthy and aged > 5 years. We are keen to invite children who may benefit from the JE vaccine because of where they live or where their family works to take part in this study. This study is taking place in NSW.

4. Do I have to be in this study?

You do not have to participate in this study if you don't want to. The doctors and nurses will take the best care of you as they have in the past, regardless of whether you are in the study or not. If you choose to participate, you can stop participating at any time. All you need to do is tell one of the researchers or your parents/carers that you don't want to take part anymore.

5. What will happen to me in this study?

If you choose to join the study, we will see you on five occasions over 12 months. All visits may be conducted by study staff at a medical facility.

You must not have had a JE vaccine previously or had JE disease. We will talk with you and your parents/guardians to check your medical history to see if you are allowed to take part in this study.

If you are able to take part in the study, you will need to have the JE vaccine and 4 or 5 blood tests over 12 months. We will randomise you to be given the JE vaccine either by SC or ID vaccination. Randomisation is like flipping a coin and this decides by chance if you are to be given ID or SC vaccination. You won't be able to choose which way the vaccine is given. After randomisation a trained doctor or nurse will then give you the vaccination. If it is given ID, we will inject a small amount (0.1ml) of JE vaccine into the skin of your upper arm. This can be painful and itchy at the site for a few days only. If it is given SC, we will inject the full standard dose (0.5ml) into your upper arm under the skin. This can cause some pain, redness and swelling lasting a few days.

Pregnancy test: Females who have started their periods will be asked to take a urine pregnancy test at visit 1 prior to the vaccine being given to make sure they are not pregnant. As JE vaccination is not recommended during pregnancy, we do not want to give the JE vaccine to anyone who may be pregnant. We also recommend that, if you are sexually active, you use birth control for 4 weeks after receiving the vaccine. The doctor will discuss this with you.

Diary card: We will give you either a paper or electronic diary card asking you to record any redness or swelling at the injection site and other symptoms you may have after vaccination. You will be given a thermometer to record your temperature each evening measured under the armpit

Blood tests: Blood samples are taken before the vaccine, one, 6 and 12 months after the vaccine. You will be asked if you want to give an extra blood sample at the day 7 visit after the vaccine, this is optional and you do not have to agree to have this blood sample taken. The blood sample will be taken by an experienced nurse immunisation specialist or paediatrician. We will need to take about 3-5mls of blood from a vein in your arm. This can be painful and bruising can occur. If you wish we can use a topical anaesthetic on your arm to reduce any discomfort associated with taking the blood sample.

We take the blood to measure the level of antibody to JE after vaccination. You and your parent will be given your individual results and their meaning.

The following table describes the five study visits.

Visit intervals and procedures

Visit Number (Timing)	**Study procedure**
Baseline **Visit 1** (Day 0) Around 1 hour visit	Explanation and discussion of the study Sign consent form Medical history and examination Blood sample collection (around 5ml) Urine pregnancy test for females (who have started their periods) Randomised to ID or SC vaccine JE vaccination Observed for ½ hour post vaccine
Visit 2 (7-10 days post visit 1) Around ½ hour visit	Medical history review Check post-vaccination adverse events Take blood sample (around 5mls) – *this is an extra sample and will only be collected if you are 10 years older and your parent/guardian agrees*
Visit 3 (28-35 days post visit 1) Around ½ hour visit	Check post-vaccination adverse events Medical history Take blood sample (around 5mls)
Visit 4	Check post-vaccination adverse events

(180-210 days post visit 1) Around ½ hour visit	Medical history Take blood sample (around 5mls) Discuss your blood test results from Visit 3
Visit 5 (12-13 months after visit 1) Around ½ hour visit	Check post-vaccination adverse events Medical history Take blood sample (around 5mls)

6. Can anything bad happen?

You may get some of the following side effects from the JE vaccine. These are usually mild and similar to side-effects seen following several routine other vaccines, like the COVID-19 vaccine you may have had.

Side effects can include feeling unwell within 48 hours of the injection, developing a fever or developing a small lump or some redness where you had the injection. After the ID injection you may find the red or hard lump is itchy. The ID injection is more painful than the SC injection.

Injection site reactions are common (local pain (>50%) and redness (30-50%)). Sometimes people who have had the JE vaccine report fever, headaches, muscle and joint pains (10-20%), chills and minor sweating, which can last several days. If you feel sick the let your parents know and they can tell the study doctors. You can take paracetamol or other similar medicine if you have fever or aches.

7. Will there be any benefits for me in this study?

We cannot promise that you will receive any benefits from this research; however, possible benefits may include some protection against future JE infection. You will know whether you were given the vaccine ID or SC. We will give you the results if your blood tests and you will know if you have made an immune response to the vaccine. If you were given the ID vaccine and the one month blood test results show that you did not make an immune response you will be offered the currently recommended vaccine a SC injection.

The results of this study may result in a change to JE vaccine recommendations in Australia and potentially allow more children, like yourself, who are at risk of JE to be vaccinated.

8. How will my privacy be protected?

Your privacy and confidentiality will be protected at all times in this study. Unless you allow us, we will not tell anybody else you are or have been a part of this study. We will not release any information to anybody else that could be used to identify you, unless we are required to do so by law. For example, researchers are required to report if a participant is believed to be at risk of harm.

All information about you (including your name, email address and mobile phone number) will be stored securely with access restricted to authorised members of the research team from the University of Sydney and research teams at your study site.

In order to protect your privacy, the study team will remove any information that may be used to identify you from any study documents, and instead of your name appearing on them, you will be

identified by a specific study code number that applies only to you. Only this code number will be used on any research-related information collected about you for this study, so that your identity as part of the study will be kept completely private. Only the study team at the National Centre for Immunisation Research and Surveillance (NCIRS) will have the ability to link this code number with your personal information, and the linking information will be kept in at the National Centre for Immunisation Research and Surveillance (NCIRS).

Your data will be stored for a minimum of 15 years after the study finishes or until the youngest participant turns 25.

If you decide to leave the study, we will not collect any more information about you. We would like to keep the information we have already collected about you to help us ensure that the results of the research project can be measured properly. Please let us know if you do not want us to do this.

9. What will happen to the study results?

We would like to share the study results by publishing them in relevant journal articles and / or presenting them at different conferences. We will make sure that information is published /presented in such a way that you are not identifiable, unless you have given us permission to do so.

You can also tell us on the consent form if you want to receive a simple summary of the study findings for information.

10. Who should I contact if I have any questions?

If you have any questions or want more information about this study before or during participation, you can talk to Professor Nicholas Wood on 0428 963 193 .

You can also ask your parents/carers to talk to us.

11. Who do I contact if I have concerns about the study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the Sydney Children's Hospitals Network HREC **(approval number: 2022/ETH02471)**.

Please talk to your parents/carers if you are worried about being in this study, or you have a complaint. They can talk to Professor Nicholas Wood on 0428 963 193 or they can contact:

- the Human Research Ethics Committee on (02) 9845 1253 or SCHN-Ethics@health.nsw.gov.au.

- the Western New South Wales Local Health District Research Governance Officer on (02) 6330 5948 or WNSWLHD-EthicsCommittee@health.nsw.gov.au (quote reference: 2023/STE03436).