T.R.I.D.L.

**T**ravellers **R**abies **I**ntra **D**ermal **L**ater boostability

RESEARCH PROJECT

* Patients who have had ID Rabies more than 5 years ago
* Will be here for 1 week to get second blood test

Time Line

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| DAY  | 0 |  | 7 | 14 |
| **Q** | Q1(Top Half)  |  |  | Q1 (Bottom Half)Give result |
| **Vaccine** | 0.1 ID  RabiesVerorab |  |  |   |
| **Test** | Serology |  | Serology  |  |
| **Location**  | Clinic |  | Clinic | Phone |

**TRIDL Participant Information Sheet**

**Travellers Rabies Intra-Dermal Later testing & boosting**

**Researchers:**

This study is being conducted at Dr Deb The Travel Doctor Clinic in Brisbane. The researchers conducting this study are:

* **Dr Deborah Mills**, Medical Director of Dr Deb The Travel Doctor Clinic in Brisbane.
* **Dr Colleen Lau** (primary investigator), an academic researcher at the Research School of Population Health at the Australian National University. Dr Lau has over 15 years of experience as a travel medicine doctor, and has conducted many research projects on travel vaccinations and travellers’ health.
* **Dr Luis Furuya-Kanamori**, NHMRC Fellow, Research School of Population Health, ANU

The ethical aspects of the study have been approved by the Human Research Ethics Committee of the **Australian National University**.

**Project Title: Travellers Rabies Intra Dermal Later testing and boosting (TRIDL)**

**General Outline of the Project:**

**A. Description and Methodology:**

Rabies is a fatal disease, present in most countries outside Australia, so poses a risk to Australian travellers. Pre exposure vaccination simplifies the treatment of animal exposures if they should occur during travel. The standard recommendations for rabies pre-exposure vaccination is to give the vaccine intramuscularly and this is valid for life.

The use of Intradermal (ID) rabies vaccine was described in 1976, with the promise of allowing cheaper protection from a disease, which has been feared throughout history. Although deaths in travellers are rare (60 reported cases 1990 – 2012), rabies risk exposures are relatively common (2-13/1000 travellers per month) In travellers who are aware the horrors of this untreatable disease, a potential rabies exposure can be stressful, and cause major disruption to travel plans in the quest for appropriate treatment.

The standard Pre-Exposure Rabies vaccination course (PrEP) of one dose ID vaccine on day 0,7,21-28 has been recommended for some time. A modified ID course of two doses of ID rabies vaccine on day 0, and 7 with one dose on day 21-28 has been documented in this clinic and published in 2011.

*Mills DJ, Lau CL, Fearnley EJ, Weinstein P. The Immunogenicity of a Modified Intradermal Pre-exposure Rabies Vaccination Schedule—A Case Series of 420 Travelers. Journal of Travel Medicine. 2011;18(5):327–332.*

This project aims to document the long term persistence and boostability of rabies antibodies in travellers who have had a course of ID rabies vaccine.

**B. Participants:** Participants will be recruited from our specialist travel medicine clinic: Dr Deb - The Travel Doctor in Brisbane. Adult Australians (≥18 years of age) who received a course of intradermal rabies vaccine more than 5 years ago, will be invited to participate. The study aims to include approximately 200 travellers.

**C. Use of Data and Feedback:** It is anticipated that the results of the study will provide valuable information to support the long term effectiveness of intradermal rabies vaccine for rabies prevention. On completion of the study, the research team plans to publish the results in an internationally recognised medical journal so that this important information can be shared with the medical and scientific community to improve the health of travellers. Individuals will not be identified when results are presented or published. A summary of the results will also be posted on the website of the clinic: www.thetraveldoctor.com.au

**D. Project Funding:** This project does not have any specific funding. It is being conducted by the doctors and nurses at the participating clinics at their own cost, with the aim of improving clinical best practice in travel medicine.

**Participant involvement:**

**A. Voluntary Participation & Withdrawal:** Taking part in this study is entirely voluntary. There are no negative consequences if you decide not to participate, and you will continue to receive the usual high standard of pre-travel and post-travel advice from the doctors and nurses. The study involves 2 questionnaires - one in the clinic and one 14 days after by phone – you will need to participate in all questionnaires but you may decline to answer particular questions.

You may decline to participate or decide to withdraw at any time without having to provide an explanation. If you decide to withdraw, your data will be excluded from the pool of results. However, once the results have been published, we will not be able to withdraw your de-identified data from the overall findings. We recommend that you read this document carefully, and discuss any questions with Dr Colleen Lau, or Dr Deborah Mills. Contact details are provided at the end of this document.

**B. What does participation in the research entail?**

To participate in the study,

1. The nurse will assist you to fill out a questionnaire with basic demographic details.
2. You will then be requested to have 10 mls (about 2 teaspoons) of blood drawn for rabies antibody level testing.
3. You will be given a single intradermal rabies booster.
4. A further blood sample will be taken 7 days later to check for rabies antibody levels.
5. You will be rung in approximately 14 days after enrollment so we can ask you if you had any side effects from the vaccine and for our nurses to give you the results of your 2 blood tests.

**C. Location and Duration:**  The consultation will take place at Dr Deb The Travel Doctor clinic in Brisbane. The standard pre travel consultation with the doctor and nurse may take up to an hour, about the same time as a standard pre-travel consultation even if you do not want to participate in the study. If you are invited to come to the clinic, specially to take part, the visit will take about 10-20 minutes.

**D. Remuneration:**  Taking part in the study will cost nothing apart from your time. The cost of the blood tests and the rabies boosters if required will be covered by the study. You will not receive any special payments for being part of this research study.

**E. Risks:** The most common side effects of blood collection are a sore arm and bruising at the site of the blood collection. The side effects of rabies boosters are sore and itchy injection site.

**F. Benefits:**

We expect that the results from this study will confirm that the intradermal vaccine provides long lasting priming of the immune system, and the findings could provide support for more widespread use of the ID schedule in travellers in the future, and lessen the need for blood tests to check immunity after 5 years.

**Exclusion criteria:**

**Participant Limitation:** You will not be able to participate in this study if:

* You have previously experienced side effects from the rabies vaccine or having blood tests
* You are pregnant
* You are on any medication that depresses your immune system
* You will be leaving within 14 days of enrollement

**Confidentiality:**

The information provided by you will only be accessible by your travel medicine doctors and nurses, and the researchers. We will need to record your name and contact details so that we can contact you for the follow-up questionnaires. We need to have your date of birth on the blood test form as it will form part of your usual medical record as it will be important for your future medical care for your treating doctors to have access to this to know how best to treat you in the event of a rabies risk exposure on an overseas trip, however, the research will only include an identifier. We will keep your participation in this research study confidential to the extent permitted by the law. However, it is possible that other people may become aware of your participation in this study. For example, The University’s Human Research Ethics Committee might inspect records pertaining to this research, but the university will ensure that your information personal remain confidential. For publication, the results of all participants will be pooled, and no individual will be identified.

**Safety Reporting**

All Serious Adverse Events (SAE) (including vaccination failure) and all Adverse Events of Special Interest (AESI) will be reported to Sanofi Pasteur Global Pharmacovigilance.

**Privacy Notice:**

In collecting your personal information within this research, the ANU must comply with the Privacy Act 1988. The ANU Privacy Policy is available at <https://policies.anu.edu.au/ppl/document/ANUP_010007> and it contains information about how a person can:

* Access or seek correction to their personal information;
* Complain about a breach of an Australian Privacy Principle by ANU, and how ANU will handle the complaint.

**Data Storage:** Medical and research records will be kept at the travel medicine clinics. Electronic data will be stored in password-protected computers owned by the clinics, the Australian National University, and the researchers. Data will be stored for a period of at least five years from the date of any publication arising from the research. After 5 years, the research data will be completely de-identified and archived at computers at the Australian National University, but your medical records will continue to be kept at the travel medicine clinics.

**Queries and Concerns:**

**A. Contact Details for More Information:** You have the right to ask any questions about this research. If you have questions, complaints or concerns related to this research, please contact one of the following people:

* Dr. Colleen Lau (Primary Investigator) Email: colleen.lau@anu.edu.au Phone: (07) 3221 9066
* Dr. Deborah Mills (Brisbane) Email: email@drdeb.com.au Phone: (07) 3221 9066

**Ethics Committee Clearance:**

The ethical aspects of this research have been approved by the ANU Human Research Ethics Committee (Protocol TRIDL 2019/453). If you have any concerns or complaints about how this research has been conducted, please contact:

Ethics Manager
The ANU Human Research Ethics Committee
The Australian National University
Telephone: +61 2 6125 3427
Email: Human.Ethics.Officer@anu.edu.au