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| Participant Information Sheet |  |
| Study title:  | *Paracetamol compared to combination pain relief in minor injury* |
| Locality: ADHB |  | Ethics committee ref.: |  |
| Lead investigator: Jay Gong |  | Contact phone number: 021140127 |  |

You are invited to take part in a study on the use of paracetamol compared to combination pain relief for minor injury. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You will have to decide whether to participate in the trial today but before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 4 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

**What is the purpose of the study?**

The purpose of the study is to evaluate whether giving a combination of pain relief is better than giving paracetamol alone. There is a lack of high quality published research in this area. There is a great variability in the choice of pain relief given to patients with similar levels of pain. This study will help guide the prescribing of pain relief in the future.

**What will my participation in the study involve?**

An emergency department (ED) staff member will come and talk to you about the study and you will be given a copy of this information sheet to read and discuss with your family or whānau. If you are willing to participate in the study, you will be asked to sign an Informed Consent form. This form shows that you have been given all the information about the study and that you understand what is involved. You will be asked to sign this form before any of the study tests take place. If you have any questions at any stage, please ask the study doctor.

If you choose to participate you will be asked how bad your pain is using a verbal scale, with zero meaning no pain and 10 meaning worst possible pain. You will then be given one of two kinds of pain relief to take whilst you are here. The two types of pain relief are the following:

Group 1:

* Paracetamol
* Placebo Ibuprofen
* Placebo codeine

Group 2:

* Paracetamol
* Ibuprofen
* Codeine

Your pain score will be reassessed after 60 minutes to see if there has been any improvement until you leave the ED. Also we will ask if you have also experienced any medication related side-effect at 60 minutes. If you are still in the ED we will ask you these questions again at 120 minutes. If the pain relief we have provided you is not enough, the clinician looking after you is able to provide you with additional medication.

**What are the possible benefits and risks of this study?**

You will be given pain relief medicine which is usual practice in our ED. We do not believe that there is any increased risk to participants over and above the risk of usual care.

**Who pays for the study?**

This is not a sponsored study. There will be no cost to you for participating in this study.

**What if something goes wrong?**

If you were injured in this study, which is unlikely, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

**What are my rights?**

Participation in this study is entirely voluntary and you do not have to take part. Your decision whether to participate will not affect your health care in any way or your future relations with the hospital. During the study you will be kept informed of anything that may influence your decision to continue to participate in the research.

If you agree to participate, you may withdraw from the study at any time. If you refuse to participate or if you choose to withdraw (at any time) this will not affect your health care or any benefits to which you are otherwise entitled.

Your participation in the study may be stopped for the following reasons:

* If you don’t follow the investigator’s instructions.
* The investigator decides it is in the best interest of your health and welfare to discontinue.

**What happens after the study?**

If you decide to participate in the study, the study doctor and research staff will collect medical and personal information about you as part of doing the study.

By agreeing to take part in this research, you will allow your medical information and results to be seen by people who check that the research was done properly.

No material which could personally identify you will be used in any reports on this study. Your personal information (for example your gender, age and medical conditions) and other information will be identified by a number (i.e. coded). The study records will be stored securely in locked offices during the study and archived in a locked cabinet for a minimum of 10 years after the study finishes. The records will then be confidentially destroyed.

## Who do I contact for more information or if I have concerns?

Principal Investigator: Mr Jay Gong Telephone: 021 420 127

Site Investigators (Auckland): Dr Peter Jones Telephone: 021 537 646

 Mrs Margaret Colligan Telephone: 021 426 336