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**PARTICIPANT INFORMATION SHEET**

***Pre-operative effects of anti-inflammatory drugs on pain and inflammation following wisdom teeth removal***

**Locality:** Department of Oral Diagnostic and Surgical Sciences, School of Dentistry

**Principal Researcher:** YJ Jessica Lee (Oral Surgery Doctorate Candidate)

**Primary Supervisor:** Mr Harsha De Silva (Senior Lecturer in Oral & Maxillofacial Surgery)

**Contact number:** (03) 479 7023

**Ethics Committee Ref:** 18/STH/139

We invite you to take part in a clinical study on the effects of pre-operative anti-inflammatory drugs on pain and inflammation following wisdom teeth surgery. 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 do not have to decide today whether or not you will participate in this study. 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 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

**What is the aim of the research project?**

This project is being undertaken as part of an Oral Surgery Doctorate degree at the University of Otago. The aim is to compare the pre-operative effectiveness of two different types of anti-inflammatory painkillers on pain, swelling, and mouth opening after wisdom teeth surgery. The medications involved in this project are **etoricoxib (Arcoxia) 120mg** and **sustained-release ibuprofen 1.6g**, two commonly used painkillers. Arcoxia is shown to be effective when given **before** bone and gall bladder operations but not much is known about its benefit in wisdom teeth surgery. Participants will be randomly assigned to a group. To help minimise bias, neither the researcher nor the participants will know which participants are receiving which medication.

**Who pays for the study?**

Application for the internal university funding is in progress.

Participants will bear the cost of surgical treatment according to the fee guidelines of the School of Dentistry, University of Otago, and the post-operative medications prescribed, except the study medications (Arcoxia, sustained-release ibuprofen) which will be provided free of charge.

**Who are we seeking to participate in the project?**

Anyone between 18 and 35 years of age who requires the removal of at least 2 impacted lower wisdom teeth are invited to participate. Participants must be healthy with no significant medical conditions and must not have any allergic reactions to anaesthetics/sedatives, anti-inflammatory painkillers (e.g. Nurofen, Voltaren), and codeine. Female patients who are pregnant or breastfeeding will not be able to participate.

**What will participants be asked to do?**

Should you agree to take part in this project, you will be asked to:

1. Complete a short questionnaire asking about things such as your age, gender, occupation, oral hygiene practice, past or present pain associated with your wisdom teeth, and whether you experience anxiety when receiving dental treatment .
2. Attend your surgical appointment. You will need to take a medication given to you 2 hours before the surgery. Before the wisdom teeth removal, your facial dimension will be assessed by a 3D scanner and your mouth opening will be measured.
3. Fill in your pain diary. This involves scoring your pain level every 3 hours (while awake) for the first 2 days after the surgery. You will also need to answer questions relating to the use of painkillers and any side effects encountered. Each occasion will take only a moment of your time.
4. Attend a review appointment with Jessica Lee 2 days after the surgery, at which time she will:
	1. Assess the extent of facial swelling and mouth opening;
	2. Collect your pain diary; and
	3. Ask you to complete a short questionnaire about your experience of pain following the wisdom teeth surgery

**Benefits and risks of participating in this study**

Surgical removal of wisdom teeth is a common procedure provided at the School of Dentistry, University of Otago. The medications provided to you before your wisdom teeth surgery are known to have a good effect in controlling post-operative pain. The effective dose of the medication will remain the same; we will be giving the medication **before** the surgery rather than after the surgery. Like all anti-inflammatory painkillers, the side effects of ibuprofen and Arcoxia may include stomache pain in some people. Despite this, ibuprofen and Arcoxia are commonly prescribed following wisdom teeth surgery. Therefore, there are no increased risks by participating in this study. It’s important that you **DON’T** combine two types of anti-inflammatory painkillers as this could increase the risk of post-operative bleeding.

We will give you a free bottle of antibacterial mouthwash and a prescription for painkillers. These painkillers are no different to those given to patients undergoing wisdom teeth surgery at the School of Dentistry.

If you believe that the painkillers provided to you by the School of Dentistry are making you feel unwell, then you are advised to stop taking those tablets and contact your medical doctor for an alternative painkiller.

**What if something goes wrong?**

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. 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 about anonymity and confidentiality?**

Your participation in this study is strictly confidential. Any personal information such as your name, age, gender, and contact details will remain anonymous. The information collected from you will be de-identified and used only by the researchers involved in this project. The de-identified information (study data) will be stored securely at the University of Otago for a period of 10 years, after which time it will be destroyed.

The results of this study will be written up in the form of a thesis and may later be summarised and published in a dental journal in order that other dentists and their patients may benefit. Nothing that could identify you will be used in anything we publish.

**If I agree to participate, can I withdraw later?**

Your participation in this research is entirely voluntary and you can withdraw at any time with no disadvantage to you. To participate you will need to fill in the accompanying consent form. You are welcome to request a copy of the final results of this research project if you desire. You have the right to access your personal data.

**What if I have any questions about the research project?**

If you require additional information, please do not hesitate to contact Jessica Lee or Mr Harsha De Silva on (03) 479 7023 during business hours.

**What if I have any problems or require additional pain relief following my wisdom teeth surgery?**

If you need to contact the oral surgery team following your wisdom teeth surgery, you may do so during business hours on (03) 479 7023. For after-hours emergency, you may contact Dunedin Public Hospital on (03) 474 0999 and ask to be put through to the on-call Dental House Surgeon.

For Māori health support, please contact Professor John Broughton, Associate Dean (Māori), Faculty of Dentistry, on (03) 479 7639.

For Health and Disability Advocacy Service, please contact 0800 555 050 or advocacy@advocacy.org.nz

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**CONSENT FORM FOR PARTICIPANTS**

***Pre-operative effects of anti-inflammatory drugs on pain and inflammation following wisdom teeth removal***

**Please tick to indicate you consent to the following**

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| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  | Yes 🞏 | No 🞏 |
| I have been given sufficient time to consider whether or not to participate in this study. | Yes 🞏 | No 🞏 |
| I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study. | Yes 🞏 No 🞏 N/A 🞏 |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | Yes 🞏 | No 🞏 |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. | Yes 🞏 | No 🞏 |
| I consent to the research staff collecting and processing my information, including information about my health. | Yes 🞏 | No 🞏 |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes 🞏 | No 🞏 |
| I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. | Yes 🞏 | No 🞏 |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. | Yes 🞏 | No 🞏 |
| I understand the compensation provisions in case of injury during the study. | Yes 🞏 | No 🞏 |
| I know who to contact if I have any questions about the study in general. | Yes 🞏 | No 🞏 |
| I understand my responsibilities as a study participant. | Yes 🞏 | No 🞏 |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

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| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

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| Researcher’s name: |
| Signature: | Date: |