##

## PARTICIPANT INFORMATION SHEET

**Overcoming dental anxiety with needle-free tooth anaesthesia**

Voluntary Participation and Withdrawal From This Study

You are being invited to take part in a research study. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. Please discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

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

This study, which will be the first in humans, aims to test a new device for the delivery of dental local anesthetic. This is a pilot study. Because many people have a fear of needles and injections, the delivery of dental local anesthetic, which makes dental treatments painless, often causes anxiety among people. Needle-free jet injection, is a technique that delivers the anesthetic as a high-speed stream, about the diameter of human hair, and has the potential to overcome dental anxiety. In this study, we will measure levels of anxiety and possible discomfort of participants who will be treated with the needle-free device and a conventional dental local anesthetic for the purposes of comparison.

**How is the study designed?**

Ten participants will be invited to participate in this study aimed at testing a new needle-free local anaesthetic injection method. Participants will be recruited from the Faculty of Dentistry.

Participants when referred for bilateral extractions (the same tooth needing extraction on both sides of your top teeth) will be screened for possible inclusion in the study. Those who meet the inclusion criteria will be given details of the study to include the patient information sheet. Participants will have ample opportunity to read the information provided, ask any questions and consent will be obtained at a subsequent appointment arranged for the extractions.

Inclusion criteria include:

* Males and females older than 18 years of age of all ethnicities;
* Participants who require planned bilateral extractions as part of a normal treatment plan. There is no additional requirement to have a diagnosis of dental anxiety;
* Participants who have no major health conditions that may affect their ability to participate in the study will be invited to participate.

**Who can take part in the study?**

You have been chosen because you need dental extractions in preparation for dentures, or as part of your orthodontic treatment, and dental local anesthetic is needed prior to these procedures.

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this Information Sheet to keep and be asked to sign a Consent form. You will have time between your appointments to consider whether you want to be involved. There will also be another opportunity to ask any questions. If you decide to take part you are still free to withdraw from the study at any time and without giving your reason. If you decide to withdraw from the study at any time, or decide not to take part in the study, this will not affect your current and future treatment in any way.

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

Your teeth will be examined by a dentist to see if you are suitable to take part in this study. If you require extractions of teeth in both sides of your upper jaw as part of your normal treatment plan and do not have other co-occurring health conditions, you will be invited to participate by an individual not directly involved in the clinical part of the study who is providing administrative support to the study. A dentist will anaesthetize (numb) one side of the jaw using a normal procedure with a needle and syringe (which is the normal standard of care), while the other side will be anaesthetized using a needle-free device that we are testing. You will not be aware which anaesthetic technique has been used on either side of your mouth. The allocation of each anaesthetic technique will be randomly allocated to either tooth on the right or left by an individual not involved in the clinical part of the study. An accepted standard test will be used to ensure the teeth are numb prior to extraction, and additional local anaesthetic will be given if needed as per normal practice.

Another dentist who will be blinded (unaware) of which anesthetic technique was used will then extract the teeth as normal. You will be asked to fill in questionnaires to measure your levels of anxiety and pain experience/discomfort after your teeth have been numbed. We would like to review you at one, three and seven days after the extractions to take photographs to check on healing and for you to complete a short questionnaire at each visit. Travel costs for these additional appointments will be reimbursed.

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

You may experience pain and discomfort as part of the anesthetic placement and extraction procedures.

You may withdraw from participation in the study at any time and without any disadvantage to yourself.

**What are the possible benefits of taking part?**

Your participation will enable us to understand whether needle-free jet injection can be used for the delivery of dental anesthetic.

The costs of two dental extractions and X-rays will be covered by the research project, in addition travel costs for your return at one, three and seven days after extractions will also be covered.

**What are the alternatives to taking part?**

Having a dentist anaesthetize (numb) your jaw with a needle and syringe (which is the normal standard of care) prior to tooth extraction.

**Will any costs be reimbursed?**

The costs of two dental extractions and X-rays will be covered by the research project, in addition to travel costs for your return at one, three and seven days after extractions are also covered. Any follow-up procedures, such as orthodontics or dentures, would not be covered by the study as they are part of your normal treatment.

**What if something goes wrong?**

If you were injured in this study, 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.

If you have any queries or concerns about your rights as a participant in this study, you may wish to contact the local Health and Disability Services Consumer Advocate:

Telephone: (03) 479 0265 or freephone 0800 377 766 or

Free fax: 0800 2787 7678 (0800 2 SUPPORT) or

Email: advocacy@hdc.org.nz

If there is a specific Māori issue or concern, please contact Prof. John Broughton, Assoc. Dean Māori.

Telephone: (03) 479 7639

Email: john.broughton@otago.ac.nz

**What will happen to my information?**

During this study the researchers will record information about you and your study participation. This includes the results of any study assessments. You cannot take part in this study if you do not consent to the collection of this information.

*Identifiable Information*

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only researchers involved with this study will have access to your identifiable information.

*De-identified (Coded) Information*

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researchers. Instead, you will be identified by a code. The researchers will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

*Security and Storage of Your Information*

Your identifiable information will be held at the Faculty of Dentistry during the study. After the study it will be transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic case report forms and kept on a secure server. All storage will comply with local and/or international data security guidelines.

*Rights to Access Your Information.*

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. Please ask if you would like to access the results of your screening and safety tests during the study. If you have any questions about the collection and use of information about you, you should ask the research team.

**What happens after the study or if I change my mind?**

If you decide to withdraw from the study prior to the placement of anaesthesia and tooth extractions, you should inform the study researchers. You will not be disadvantaged in any way by this. Your treatment will be provided as originally planned following the normal standard of care.

**Can I find out the results of the study?**

The results will be subjected to statistical analysis to determine if the new device offers significant benefit to participants.

In accordance with normal practice, the researchers plan to publish the results in an appropriate journal in due course. All participants who take part in the study will be provided with a lay summary of the results if they wish. You will not be identified personally in any publication arising from this study.

**What if new information becomes available?**

While you take part in the study new information could become available about your treatment. You will be told if this happens and you will alwayshave the choice of leaving the study at any time. If you leave the study, your normal care will continue. If you continue with the study, you will be asked to sign an updated consent form. If some new information becomes available, your research dentist may advise you to leave the study in your best interests. Any reasons for doing this and arrangements will be explained to you.

**Who is organising and funding the research?**

This study is organised by Prof. Paul Brunton, Faculty of Dentistry. The study has been funded by a MedTech Core grant. It is possible in the future that this may well result in a commercial device that a dentist may use. Please note participants would not benefit individually if a commercial device for use by dentists results from this research project. None of the research team conducting this clinical study will be paid for carrying out the research. The costs associated with two extractions and X-rays will be covered by the study, in addition to the travelling costs for returning visits at one, three and seven days.

**Who has approved the study?**

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The HDEC Northern Committee has approved this study.

**Contact for further information**

If you require any further information then please feel free to discuss this with Prof. Paul Brunton at the Faculty of Dentistry, University of Otago, telephone 03 479 7413.

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email:

advocacy@hdc.org.nz

Website: https://www.advocacy.org.nz/

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### CONSENT FORM

**Overcoming dental anxiety with needle-free tooth anaesthesia**

**Please tick to indicate 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.  |  |  |
| I have been given sufficient time to consider whether or not to participate in this study. |  |  |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. |  |  |
| 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. |  |  |
| 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. |  |  |
| I consent to the research staff collecting and processing my information, including information about my dental health. |  |  |
| 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. |  |  |
| I consent to my dentist being informed about my participation in the study and of any significant abnormal results obtained during the study. |  |  |
| 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. |  |  |
| I understand the compensation provisions in case of injury during the study. |  |  |
| I know who to contact if I have any questions about the study in general. |  |  |
| I understand my responsibilities as a study participant. |  |  |
| I wish to receive a summary of the results from the study. |  |  |

**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: |

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