Participant Information Sheet (Participants with xerostomia)

Project title: A study to determine the most appropriate dose form and flavour for oral treatment of dry mouth with pilocarpine

You are invited to participate in our study to taste some dosage forms and tell us what you think of them. Please read the information below. **If you are willing to participate please contact the principle investigator, Rose Estafanos, to make an appointment.**

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WHAT IS THE STUDY ABOUT?

Xerostomia is a major problem that many people experience, especially those who have received radiotherapy for the treatment of head and neck cancer. Saliva plays many vital roles in our daily life and people with reduced saliva production can experience a variety of health problems.

Pilocarpine is a drug that can stimulate saliva production, and is available as tablets or capsules in some countries for treating dry mouth. In Australia, pilocarpine is only available as eye drops to treat glaucoma. The eye drops have a bad taste when taken by mouth to stimulate saliva production.

This study investigates two dosage forms for their potential use in pilocarpine delivery for stimulating saliva production: troches (a cross between a lozenge and pastille that dissolves slowly in the mouth) and orally dissolving tablets (little tablets that dissolve rapidly in the mouth). Both the troches and orally dissolving tablets can be prepared in pharmacies with compounding services.

WHAT WILL YOU BE ASKED TO DO?

Participation is voluntary. The study will take place at the Pharmacy Australia Centre of Excellence (PACE) building, 20 Cornwall St, Woolloongabba and is expected to take 30-60 minutes. You will be provided with specific details on location, transport and free parking.

You will be asked to:

1. Briefly taste five troches containing 5 mg pilocarpine, each with a different flavour, and spit them out after 10 seconds, then indicate the acceptability of each troche; and drink some water between tasting each troche.
2. Take a non-medicated orally dissolving tablet and a non-medicated troche, allowing each to completely dissolve in your mouth. Indicate your preferred dosage form.
3. Complete a written questionnaire about your age, gender, ethnicity, health, medications, flavour preferences and the cause, progression and treatment of your xerostomia.

ARE YOU ELIGIBLE TO PARTICIPATE IN THIS STUDY?

It is recommended that you seek advice from your treating medical practitioner about your eligibility to participate, because if you experience any of the following, you will not be able to take part in this study:

- Problems with your eyes which may be made worse with the medicine you will taste. For example, problems of the iris (coloured part of the eye) or glaucoma.
- A co-existing medical problem that is not well controlled and there is a risk of it worsening, or where a change to active treatment is contemplated. For example, severe or uncontrolled asthma or pulmonary disease, uncontrolled low or high blood pressure, overactive thyroid, uncontrolled seizures or heart rhythm problems (especially prolonged slow heart rate – a pacemaker doesn't prevent you from participating) or Parkinson's disease
- Known hypersensitivity to pilocarpine
- An active oral infection i.e. thrush, cold sores, shingles, or mouth ulcers.
- Suspected or confirmed pregnancy.

You should also be able to understand written English language.

IS THERE ANY RISK IN PARTICIPATING?

Pilocarpine is contained in the five flavoured troches that you will be briefly tasting and then spitting out. The usual dose for stimulating saliva production is 5 mg. Based on a previous pilot study, we know that you should expect to swallow a total of approximately 2 mg pilocarpine during the taste testing. This is expected to be sub-therapeutic, so effects are unlikely. If you do experience any effects, the most likely are a brief period of increased saliva, tear and urine production.

The other components in the troches and orally dissolving tablets are commonly used in foods and pharmaceuticals. Adverse reactions to the components are unlikely. They are sweetened with the natural sweetener stevia and do not contain any sugar.

IS THERE ANY BENEFIT IN PARTICIPATING?

There isn't any immediate benefit in your participation in this study, but ultimately you will be helping to make a pleasant and effective dosage form available to Australian people living with xerostomia. Refreshments will be available after completing the study and you will receive a $30 Coles/Myer voucher as reimbursement for travel to the study location at PACE.

WILL YOUR PRIVACY BE RESPECTED?

This study is confidential. We will collect information that can be used to identify you. Your full name, address and date of birth will be collected on a separate form, kept in a locked cabinet under the supervision of the Project Coordinator and only accessed in the unlikely event that we need to contact you regarding the study or if you wish to withdraw from the study. The only identifier that will link your contact details to data collection sheets will be your participant number. Data sheets and contact details forms will be stored for 7 years and then shredded. Data collection sheets will be transferred into Excel spreadsheets for analysis, and these will be password-protected and stored on the Investigator's computers indefinitely. This data (which does not contain any information that can be used to identify you) may be shared with other researchers.

Participation is completely voluntary and you are able to withdraw at any time.

Thank you for your time. A summary of the results from this study will be available on request. If you are interested, please contact one of the investigators.

This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your participation in this study with project staff (contactable on 3346 1886 or email k.steadman@uq.edu.au), if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinator on 3365 3924.