PARTICIPANT INFORMATION SHEET

Date Created: March 2019

No. Pages: 5 **Review Date: March 2019**

Future Review Date:

(Consent Form MUST accompany this document) Refer to Section 5.2.16 of the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates.

1. **Study Title: The Clinical Benefit of using Azithromycin in Non-Surgical Periodontal Therapy in Advanced Disease in Patients where Initial Treatment has not been successful**

2. **Investigators: Prof Saso Ivanovski, Dr Roderick Marshall, Dr Ryan Lee, Srinivas Sulugodu Ramachandra**

3. **Introduction:-**

You have been asked to take part in a clinical research study. This is because your initial periodontal disease therapy has not completely resolved your disease as assessed by persistence of deep pockets and bleeding from these pockets. This can mean that you could need further cleaning of the teeth or surgical periodontal therapy to completely control your disease. Patients often find surgical therapy costly and invasive. The research project is testing the addition of an antibiotic to the retreatment of your teeth by further root surface cleaning and oral hygiene instruction. The new antibiotic is called Azithromycin.

This Participant Information Sheet and Consent Form tells you about the research project. It explains the purpose of the research, procedures and risks involved. It also describes information about you that will be obtained, how that information will be used and with whom it will be shared. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor. Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part. If you decide you want to take part in the research project, you will be asked to sign the Consent Form.

By signing it you are telling us that you;

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to use of your personal and health information as described

You will be given a signed and dated copy of this Participant Information Sheet and Consent Form to keep.

4. **Purpose of the Study: -**

You are invited to participate in a research study, which is being conducted in order to test whether the use of Azithromycin (an antibiotic) in conjunction with conservative retreatment of your disease might improve the health of your gums and avoid the need for surgical periodontal therapy to fully control your disease. It is also designed to test

whether the responses anticipated are as a result of the antibiotic or immune effects of this drug.

5. Study Procedures:

5.1 Treatment Schedule

The clinical trial will last for 12 months. Normal clinical recordings will be undertaken at retreatment, 3 months, 6 months, 9 months and 12 months. Radiographs will be taken initially and at the end of the trial at 12 months. Saliva, dental plaque samples and samples from the fluid in the pockets around your teeth will also be taken at each time period.

5.2 Length of Treatment Time Including Length of Each visit

Treatment	Time	Charting	Saliva	Plaque	GCF	X-Ray
Records & Treat	90 min					
Retreat	60 min	√	√	√		√
3 month	60 min	√	√	√	√	
6 month	60 min	√	√	√	√	
9 month	60 min	√	√	√	√	
12 month	90 min	√	√	√	√	√

The treatment you will receive will be similar to the non-surgical treatment you have already received. This will involve further cleaning of your tooth surfaces and ongoing discussions about best ways to improve your oral hygiene effectiveness and efficiency. This treatment will be undertaken by a registered specialist periodontist (Prof Saso Ivanovski). This retreatment has been documented to have beneficial effects but may still not fully control your disease. Half of the subjects enrolled in the study will be given Azithromycin (daily 500 mg dosage for 3 days) and other subjects will receive a placebo (inactive drug) and this will be assigned on a random basis so both you and the clinician do not know which drug you have taken. All subjects that continue to show signs of disease activity will be offered further treatment options (including the drug being tested) for their disease at the end of the trial.

6. Risks and Discomforts:-

The relatively slow progression of disease means that the proposed trial and any delay in offering other forms of therapy is unlikely to result in further progression of your disease or reduce the possible effect of other therapies you might be offered or accept at the end of the clinical trial. Normal slight discomfort that can be relieved with over the counter analgesics may occur but it is likely that this may be less than you have experienced during your previous therapy. Local anesthetic will be offered if you require this.

Azithromycin is a commercially available antibiotic that has been shown to have few side effects. Azithromycin is generally well tolerated, but relatively common adverse effects (1–5% of patients) include gastrointestinal upset, headache and dizziness.
It has been reported that Azithromycin can interact with patients that have cardiac arrhythmias. Although this is an exclusion point from the study, if you have any concerns about heart problems while taking the drug you will be able to contact the research team at any time.

7. Ionising Radiation

The proposed radiographs hold slight but measurable risk. These radiographs would be considered as a normal requirement to measure your disease progression.

8. Possible Benefits:

The treatment you will receive will improve the health of your gums and may help you to avoid tooth loss. It is anticipated that the addition of the antibiotic may further improve the health of your gums to a state where less maintenance is needed or surgical periodontal therapy is avoided.

Alternatives to participation:- If you elect not to participate in the study you will still be offered all possible treatment options including non-surgical re-treatment and surgical therapy to control your disease.

9. Tissue Donation:-

All tissue samples (saliva, crevicular fluid and plaque) are required for this study. They will be destroyed immediately following completion of sample testing

11. Voluntary Participation/Right to Refuse or Withdraw:-

There is no obligation for you to be involved in this study. If you do not participate your normal treatment plan will be followed. If you decide to participate in the study and later feel that you no longer wish to be part of it, you may withdraw from the study at any time without prejudice to any current or future medical treatment.

12. Confidentiality:-

Your records relating to this study and any other information received will be kept strictly confidential. However staff participating in your care, the sponsor and other agencies authorised by law, may inspect the records related to the study. In the event you are admitted to hospital as a result of an adverse event resulting from this study, your treating doctor may require access to your study records.

Your identity will not be revealed and your confidentiality will be protected in any reviews and reports of this study which may be published. However, results may be suppressed for commercial reasons as the sponsor of the project retains the rights to the data.

Your treating Doctor/s will be notified of your participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.

Please refer to Confidentiality/Privacy Policy PI025 available at www.bellberry.com.au for further information.

13. Costs

Some of the tests or treatments used in this study may be part of standard care used to maintain your health even if you did not take part in the study. All medication and study-related tests will be provided at no cost to you.

14. Illness or Injury

If, as a result of being in this study, you become ill or are injured, please immediately contact your study doctor. She or he will then give you all necessary information and treatment and will inform the trial sponsor.

15. Compensation for Injury

If you are injured as a result of your participation in this trial you may be entitled to compensation. Sponsors of clinical trials in Australia have agreed that the guidelines developed by their industry body, Medicines Australia, will govern the way in which compensation claims from injured participants are managed by sponsors.
However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines.
These guidelines are available for your inspection on the Medicines Australia Website (www.medicinesaustralia.com.au) under Issues/Information – Clinical Trials – Indemnity & Compensation Guidelines. Alternatively, your study doctor can provide you with a hard-copy of the guidelines.
It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.

16. Termination of the Study

This research project may be stopped for a variety of reasons. These may include the following: Unacceptable side effects, the drug being shown not to be effective, the drug being shown to work and not need further investigation and decisions made in the commercial interests of the sponsor.

17. Investigators Benefits

Your study doctor is not being remunerated to conduct this study.

18. New Information Arising During the Project

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.

19. Results of Project

It is the intent of the investigators that the results of this clinical trial will be published in high quality peer reviewed scientific journals and should you so desire you can be provided with a copy of the publication.

20. Consent

Your study doctor is required to provide you with all information regarding the nature and purpose of the research study, risks/benefits and the possibility of alternative treatment and you should be given the opportunity to discuss these. It must be stated that you are free to withdraw anytime and that if you do not participate you will not suffer any prejudice.

21. Advice and Information

If you have any concerns or complaints about this project before, during or after the trial you can contact the chief researcher as follows:

Prof Saso Ivanovski
Phone: +61 7 336 58064
Hand Phone: 0412233081
Email: s.ivanovski@uq.edu.au

You may also make any complaints in a confidential manner to the Bellberry HREC by contacting the Chief Executive Officer Bellberry Limited, 129 Glen Osmond Road, Eastwood 5063. Telephone 08 8361 3222. bellberry@bellberry.com.au.

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Committee Chair, Bellberry Human Research Ethics Committee on 08 8361 3222.

All study participants must be provided with a signed and dated copy of the Participant Information Sheet and Consent Form for their personal records.