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| Participant Information form |
| Clinical and Microbiological Assessment of Full mouth disinfection in conjunction with systemically administered Azithromycin : A randomised controlled clinical trial |

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**PARTICIPANT INFORMATION FORM**

Dear Sir/Madam,

Please be assured that your general well-being is vital and is our ultimate concern. We will always strive to provide you with quality periodontal treatment at all times.

Our primary target is to treat your gum disease and prevent any further advancement of the gum disease that may lead to tooth loss in the future.

Please be advised that your participation is voluntary at all time. If you decide not to participate in our study, your decision will not have any negative impact on you or your treatment and you will still receive complete periodontal care.

**PURPOSE OF THE STUDY:**

Chronic periodontitis (gum disease) is caused by millions of bacteria building up around your teeth over the years. This build up causes the bone holding your teeth to gradually dissolve. In advanced stages, as more bone dissolves, your teeth become loose and you might eventually lose them.

The key to treating gum disease is to do thorough scaling and cleaning of the roots of your teeth (also called subgingival root debridement) usually done during multiple visits ( 4- 6 visits) . Recent studies have shown that some bacterial can transfer from the untreated sites to the clean, treated sites between visits, thus it has been proposed that one stage disinfection protocol is superior, as the treatment of all sites is carried out in only 2 visits within 24 hours , along with use of antibacterial mouthwash during and after treatment in order to eradicate the bacteria around teeth and in the mouth.

Many studies have also proved that oral antibiotics also help in conjunction with the one stage disinfection protocol, as they remove the bacteria from the areas that are difficult to manually instrument.

The aim of this study is to test whether antibiotics provides any additional beneficial effects in terms of clinical outcomes to the one stage full mouth disinfection protocol

**WHAT IS MY ROLE**

When you come and see us, we will carry out the standard procedures normally done to all patients with moderate to advanced chronic periodontitis:

1. We will give you detailed oral hygiene instructions & quick clean in first visit
2. We will examine your gums thoroughly and collect some bacterial samples & review your oral hygiene.
3. We will clean you gums thoroughly in 2 visits within 24 hours
4. We will give you mouthwash to use 2 times a day for 14 days

AND THEN, you will be assigned to one of three groups:

1. Azithromycin group: This is the antibiotic we are testing.
2. No antibiotics: If you are part of this group, you will be given starch tablets which have no effect.

**Note that you will not be informed which tablets have you been given, until the end of the study. Your dentist will also not know which tablets you are receiving.**

**There is no additional charge for the drugs and mouthwash.**

We will then see you after 2 weeks to make review your oral hygiene instructions and ask you to fill a questionnaire regarding any side effects. WE will also see you in three months after treatment and re-examine your gums and collect some bacterial samples. Finally we will see you in 6 months to review the condition of your gums again.

Finally, we will run some statistical analysis to find out how those antibiotics have helped with your gum condition.

**HOW MANY VISITS DO I HAVE TO ATTEND:**

You need to attend 7 visits:

1. The first visit is the initial examination to your gums and collect some bacterial samples from your mouth (approx. 90 minutes)
2. The second, and third visit (within 24 hours) is to clean your gums
3. After 14 days: The next visit is to check how good your oral hygiene is. It will be explained to you later how oral hygiene (brushing and flossing) are very important for your gums to heal.(approx. 30 minutes),
4. After 3 months: a visit is to re-examine your gums and collect some bacterial samples. (approx. 90 min)
5. After 6 months.: re examine your gums ( 90 min)

**DRUG DOSES:**

1. Azithromycin (500mg): One tablet per day for three days.
2. Chlorhexidine mouthwash 2% ( use 2 times a day for 14 days)

**It is important that you take the medications as instructed.**

**IMPORTANT INFORMATION ABOUT THE MEDICATIONS:**

Azithromycin, is not a recently introduced drugs. Millions of people use them all over the world.

Just like all medications, this drug also may have some side effects, even though they are rare, you need to be informed about them, possible side effects include,

hypersensitivity, nausea, abdominal pain diarrhoea and anaphylaxis (rarely)

Medical care should be sought if any severe symptoms arise.

Finally, your contribution to the study will be appreciated as will be helping dentists find answers to questions.

Your participation in this study does not prejudice any right to compensation, which you may have under statute or common law.

All data related to you will be handled with full confidentiality. Information will be stored safely in a computer which is only accessible by *Dr Alessandro Quaranta, Dr Julio Rincon* and *Dr Eman Elhassan* .

The data will be securely destroyed after a period of seven years, unless it is needed for further research, in which case approval from you and from the Human Research Ethics Office (HREO) will be requested first.

Many thanks.

***Approval to conduct this research has been provided by the University of Western Australia, in accordance with its ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time.***

***In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the Human Ethics Office at the University of Western Australia on (08) 6488 3703 or by emailing to***[***humanethics@uwa.edu.au***](mailto:humanethics@uwa.edu.au)

***All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project***