

07-Jun-16

Dr. Vincent O'Rourke
The University of Queensland
Room 7218, Oral Health Centre, Cnr Brampston Tce and Herston Rd
Herston QLD 4006

Dear Dr. O'Rourke,

Re: Application No: 2016-03-262

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.

Application Type: NEW

Type of Review: FULLBOARD

Name of the Documents Submitted & Approved: Attachments

AZI Initial Clinical Trial V2.1

Protocol Signature Page

Patient information sheet AZI Trial v 2.0

Consent Initial AZI Study v1.2 Clean

Azithromycin CMI

Team Quality and Capability AZI

Team Track Record AZI

Date of Meeting: 18-May-16

Date of Approval: 07-Jun-16

Period of Approval: 07-Jun-16 - 31-Dec-18

Thank you for submitting the above mentioned application.

The Bellberry Human Research Ethics Committee (HREC) reviewed this study in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates as at May 2015) (National Statement) on the above meeting date.

This Bellberry HREC is constituted and operates in accordance with the National Statement.

I wish to advise that the Bellberry Human Research Ethics Committee has approved this project and that the application meets the requirements of the National Statement subject to the conditions mentioned below.

CONDITIONS:-

- **THAT YOU ACKNOWLEDGE YOUR AGREEMENT TO THE UNDER MENTIONED CONDITIONS BY SIGNING AND RETURNING A COPY OF THIS LETTER, PRIOR TO THE COMMENCEMENT OF THE RESEARCH. THE SIGNED LETTER CAN BE EMAILED TO BELLBERRY@BELLBERRY.COM.AU OR POSTED TO THE ABOVE ADDRESS.**
- The data collected for the purpose of this research project cannot be used for any other purpose without the approval of the Bellberry Human Research Ethics Committee. Requests to use this data for other purposes must be made in the form of a formal research proposal.
- All research data, including electronic data is to be stored by the Principal Investigator for 15 years after the research has



been completed or after the last contact, whichever is the later. Data must be recorded in a durable and appropriately referenced form and comply with relevant privacy protocols.

- That copies of all completed consent forms and any other data used in this research may be inspected at any time by representatives of the Bellberry Human Research Ethics Committee.
- That a report on the progress of the research will be made to the Bellberry Human Research Ethics Committee on **07-Jun-17** or on completion of the trial (if sooner) and then annually for the duration of the trial. This report is to indicate whether any ethical problems or complications have arisen, particularly side effects of drugs used or any other factor which may result in the investigation not producing any result as distinct from the anticipated result.
- That you will notify the Bellberry Human Research Ethics Committee of any changes that may be required within the research proposal.
- Bellberry Human Research Ethics Committee approval is conditional upon your meeting any statutory obligations that you may have in relation to this project.
- Adverse Event reporting should be reported to the Bellberry Human Research Ethics Committee as per the monitoring guidelines posted on the website www.bellberry.com.au.
- Any extension to the initial approval period is to be requested in an application via the eProtocol system together with the inclusion of a progress report.
- That you will provide a copy of the Sponsor's final report when this becomes available.

Details of Ethics Committee:

It is the process of the Bellberry Human Research Ethics Committee not to disclose personal details of its reviewing members. This Project was considered by a Committee that fulfilled the requirements of the National Statement (2007) section 5.1.29-30. A member listing is available as an attachment in eProtocol. Please note that the Principal Investigator and Co-Investigators are not members of the Bellberry Human Research Ethics Committees and were not involved in the review of this study.

This study has been given the above reference number. Please remember to log on to eProtocol for all further correspondence with the Committee.

Please do not hesitate to contact me if further clarification is required.

Yours sincerely

Brian Stoffell
Chair, Committee A (TGA HREC Code: EC00372)
BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

PRINCIPAL INVESTIGATOR SIGNATURE DATE

29-May-18

Dr. Vincent O'Rourke
The University of Queensland
Room 7218, Oral Health Centre, Cnr Brampton Tce and Herston Rd
Herston QLD 4006

Dear Dr. O'Rourke

Re: Application No: 2016-03-262-PRE-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.

Type of Review: Progress Report/Ethics Approval Extension

Name of the Documents Submitted:

See below:

Attachments

Includes:

Extension of ethics approval to 30 December 2019. Progress Report dated 23 May 2018.

Date Noted/Approved: 29-May-18

Thank you for submitting the above mentioned application.

The Bellberry Human Research Ethics committee (HREC) has scientifically and ethically reviewed this study.

This Bellberry HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates as at May 2015) (National Statement).

I wish to advise that the Bellberry Human Research Ethics Committee has noted the progress of this study.

Details of Ethics Committee:

It is the process of the Bellberry Human Research Ethics Committee not to disclose personal details of its reviewing members. This Project was considered by a Committee that fulfilled the requirements of the National Statement (2007) section 5.1.29.30 including a minimum of people in the following categories:

- chairperson (a)
- layman (b)
- laywoman (b)
- person/s with counselling experience (c)
- two persons with research experience (f)
- pastoral carer (d)
- lawyer (e)

Please do not hesitate to contact me if further clarification is required.

Yours sincerely





129 Glen Osmond Rd
Eastwood SA 5063
Phone: 08 8361 3222
Fax: 08 8361 3322

Brian Stoffell
Chair, Committee A
BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

25-Jun-18

Dr. Vincent O'Rourke
The University of Queensland
Room 7218, Oral Health Centre, Cnr Brampston Tce and Herston Rd
Herston QLD 4006

Dear Dr. O'Rourke

Re: Application No: 2016-03-262-A-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.

Type of Application: Amendment/Investigator Brochure Form

Name of the Documents Submitted and Approved:

Attachments

Includes:

The following sites will be conducting this study with Dr Vincent O' Rourke as the Principal Investigator:

1. Brisbane City Periodontics and Implants, 141 Queen St, Brisbane City QLD, and
2. Brisbane City Periodontics and Implants, Metropol II Shopping Centre, Cnr of Creek and Pine Mountain Road, Mount Gravatt East, QLD.

The Committee noted this information and extend ethics approval to cover these sites.

The Committee also noted the addition of the following Co-Investigators:

- Professor Saso Ivanovski
- Dr Roderick Marshall
- Dr Ryan Lee
- Mr Srinivas Sulugodu Ramachandra

The responsibilities of the Co-Investigators are as follows.

- Professor Saso Ivanovski and Dr Ryan Lee are registered periodontists working at School of Dentistry, The University of Queensland and Brisbane City Periodontics and Implants.
- Dr Roderick Marshall is a registered periodontist working at the Brisbane City Periodontics and Implants.
- Professor Saso Ivanovski, Dr Roderick Marshall and Dr Ryan Lee will be recruiting patients, obtaining informed consent, and treating patients(providing non-surgical periodontal therapy and either azithromycin or placebo).
- Srinivas Sulugodu Ramachandra will be responsible for the collection of patient samples and related research work to be carried out in the research lab of the School of Dentistry, The University of Queensland.

Date of Approval: 22-Jun-18

Thank you for submitting the above mentioned application.

The Bellberry Human Research Ethics committee (HREC) has scientifically and ethically reviewed this study.

This Bellberry HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates as at May 2015) (National Statement).

I wish to advise that the Bellberry Human Research Ethics Committee has ethically approved these documents/changes.

Details of Ethics Committee:

It is the process of the Bellberry Human Research Ethics Committee not to disclose personal details of its reviewing members. This Project was considered by a Committee that fulfilled the requirements of the National Statement (2007) section 5.1.29-30. Please note that the Principal Investigator and Co-Investigators are not members of the Bellberry Human Research Ethics Committees and were not involved in the review of this study.

Please do not hesitate to contact me if further clarification is required.

Yours sincerely



Brian Stoffell

Chair, Committee A (TGA HREC Code EC00372)

BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

12-Mar-19

Professor Saso Ivanovski
The University of Queensland
Oral Health Centre Herston, 288 Herston Rd
Herston QLD 4006

Dear Professor Ivanovski

Re: Application No: 2016-03-262-A-2

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.

Type of Application: Amendment/Investigator Brochure Form

Name of the Documents Submitted and Approved:

Attachments

- Clean Copy Consent Form 1.3
- Clean Copy Participant Information Sheet 3.0
- AZI Initial Clinical Trial V3.0 Clean copy
- Protocol signature page
- New_CMI

Includes:

The Committee approves the change of PI from Dr Vincent O'Rourke to Prof Saso Ivanovski. The 'Study Sites' and 'Personnel Information' pages have also been updated as part of this amendment to reflect this change.

Date of Approval: 12-Mar-19

Thank you for submitting the above mentioned application.

The Bellberry Human Research Ethics committee (HREC) has scientifically and ethically reviewed this study.

This Bellberry HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates as at 2018) (National Statement).

I wish to advise that the Bellberry Human Research Ethics Committee has ethically approved these documents/changes.

Details of Ethics Committee:

It is the process of the Bellberry Human Research Ethics Committee not to disclose personal details of its reviewing members. This Project was considered by a Committee that fulfilled the requirements of the National Statement (2007) section 5.1.29 & 5.1.30. Please note that the Principal Investigator and Co-Investigators are not members of the Bellberry Human Research Ethics Committees and were not involved in the review of this study.

Please do not hesitate to contact me if further clarification is required.

Yours sincerely





129 Glen Osmond Rd
Eastwood SA 5063
Phone: 08 8361 3222
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Brian Stoffell

Chair, Committee A, TGA Code: EC00372

BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

Notes:

As per original approval letter for Dr Vincent O'Rourke dated 07 June 2016, I agree to maintain the original Conditions of Approval for the above study.

NAME

DATE

e-protocol

03-Apr-19

Professor Saso Ivanovski
The University of Queensland
Oral Health Centre Herston, 288 Herston Rd
Herston QLD 4006

Dear Professor Ivanovski

Re: Application No: 2016-03-262-A-3

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.

Type of Application: Amendment/Investigator Brochure Form

Name of the Documents Submitted and Approved:

Attachments

AZI Initial Clinical Trial V4.0 clean copy

Date of Approval: 03-Apr-19

Thank you for submitting the above mentioned application.

The Bellberry Human Research Ethics committee (HREC) has scientifically and ethically reviewed this study.

This Bellberry HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates as at 2018) (National Statement).

I wish to advise that the Bellberry Human Research Ethics Committee has ethically approved these documents/changes.

Details of Ethics Committee:

It is the process of the Bellberry Human Research Ethics Committee not to disclose personal details of its reviewing members. This Project was considered by a Committee that fulfilled the requirements of the National Statement (2007) section 5.1.29 & 5.1.30. Please note that the Principal Investigator and Co-Investigators are not members of the Bellberry Human Research Ethics Committees and were not involved in the review of this study.

Please do not hesitate to contact me if further clarification is required.

Yours sincerely



Brian Stoffell

Chair, Committee A, TGA Code: EC00372

BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE