Study reference number:	18/CEN/237
Short title:	IM DRY
Co-ordinating Investigator (CI):	Dr Leesa Morton
Date approved:	14/12/2018

Post-approval Form Filter

Filter. Which of the following post-approval items would you like to submit?

- ○ an amendment
- ◉ a progress report
- ○ a protocol deviation or violation
- ○ a report of a serious adverse event (to SCOTT only)
- ○ notification of conclusion of the study
- ○ a final report

Progress Report

P1. What is the current status of your study?

If your study is the New Zealand arm of an international study, please answer the questions below for the New Zealand arm only.

- ○ This study has been abandoned prior to commencement
- ○ This study is yet to commence
- ◉ This study has commenced and is continuing
- ○ This study has concluded

P4. On what date did this study commence?

14/03/2019

P5. On what date do you expect this study to conclude?

31/12/2022

Administrative Section

P6. Are there any new study sites (localities) since the last annual progress report, or if this is the first report, since approval?

- ○ Yes
- ◉ No

P7. Has there been any change to the Sponsor since the last annual progress report, or if this is the first, since approval? If the study is not sponsored please select ‘not sponsored study’.

- ○ Yes
- ○ No

◉ Not sponsored study

P8. Clinical Trials Registration: Does this study require registration on a clinical trial registry?

◉ Yes
○ No
○ Not Applicable

P8.1. Please state what registry the trial is registered with and provide a link to the study.

[< 600 characters]

ACTRN12619000132145
https://www.anzctr.org.au

P9. Funding Status/Changes: Select the appropriate box that best describes the funding status of this study.

○ Not funded
○ Pending
◉ Awarded
○ Funding has ended
○ New funding source

P10. Please explain your answer to P9.

[< 600 characters]

A+ Trust Research award for direct costs relating to the study including regulatory site documents, stationary and consumables (mouthwash).

P11. Since your approval, or the last progress report, has the study been audited or reviewed by a third party? For example by the sponsor, a funding agency or an external provider.

○ Yes
◉ No

P12. Does the study have data safety monitoring arrangements? For example an individual monitor or a data safety monitoring committee.

◉ Yes
○ No

P12.1. Please explain whether the monitor has produced any recommendations, suggested any changes to the study **and** indicate whether there have been any changes to the composition of the reviewing body.

[< 600 characters]

An independent Data Monitoring Committee (DMC) has been established and will be responsible for monitoring the safety and efficacy of data collection and reviewing trial conduct at all recruiting sites and make recommendations to the trial steering committee. There have been no safety issues to report for this study.

Commercial Studies and Claims

P13. Is this study a commercially sponsored intervention study?

- ○ Yes
- ◉ No

P14. Has the conduct of this study over the past year complied with all relevant ethical standards?

- ◉ Yes
- ○ No

P15. Please briefly explain your answer in P14.

[< 600 characters]

All international and national ethical standards are in place, with regular site meetings with the CI to discuss study progress, any issues and education of new investigators (registrar and fellow change over at the end of 2020/Q1 2021).

Non-substantial Changes Update

P16. FOR HDEC - Please briefly describe any minor (non-substantial) amendments **and** protocol deviations or violations that have been made or occurred to this study since the previous progress report (or, if this is the first progress report, since the study commenced).

Please upload any new versions of documents that contain non-substantial amendments. This includes minor changes to advertising, PIS/CF etc. **Note** you do not need to submit all localised versions of the PIS/CF.

FOR SCOTT - Please briefly describe any minor (non-substantial) amendments that have been made to this study since the previous progress report (or, if this is the first progress report, since the study commenced).

[< 1200 characters]

There have been no amendments to the study since the previous progress report.

Recruitment Update

P17. Please indicate how many participants have been recruited to this study in New Zealand, and whether recruitment is on target.

If your study involves human tissue and/or health information rather than human participants, please enter "0" and "on target".

96

- ◉ behind target
- ○ on target
- ○ ahead of target

P18. Please list recruitment by site:

[< 600 characters]

Counties Manukau (Middlemore and Manukau super clinic) - 6
Christchurch - 50
Northland - 14
Waikato - 0
Auckland - 26

P19. Have any participants voluntarily withdrawn from this study?

- ○ Yes
- ◉ No

P20. Have any participants been withdrawn by the Investigator?

- ○ Yes
- ◉ No

Maori Consultation Update

P21. Has Maori consultation occurred since or before initial HDEC approval?

- ◉ Yes
- ○ No

P21.1. Please briefly describe the Maori consultation process that has occurred for your study at each site. For instance, were any issues identified with your study? Have any changes been required of your study or patient information? Are you conducting on-going consultation?

[< 1200 characters]

Individual sites have presented the study to their research offices and Maori health advisers for support and recommendations.

Summary of report

P22. The progress report should provide the HDEC with a description of the progress of the study over the past approval period, and the study's current status. Please provide a summary for the reviewing HDEC outlining:

- Progress towards achieving research objectives;
- Barriers to meeting research objectives, and strategies to overcome barriers;
- Your analysis of the study's adverse events and unanticipated problems and any effect on the research;
- Any scientific developments affecting the equipoise, safety, efficacy or other fundamental aspect of the study;
- Your opinion as to whether the risk/benefit ratio for the study remains reasonable;
- For community based studies, have any findings have been shared with the local community?
- Any other relevant comments.

[< 1200 characters]

The study is progressing along slower than expected, some of this relates to the COVID 19 and the impact on trainees and their advance anaesthesia programme, with exams and placements being rescheduled and delayed. Clinical case loads during this period and reduced unnecessary interaction with patients for three months March - June resulted in no recruitment during this time. Winter months where bed allocations for elective patients are effected by the acute medical admissions to the hospitals involved has also played a significant role in the ability to achieve targets for each centre and initiation of new sites.

P23. *An annual safety report must be attached if your study involves a new medicine. Please upload an annual safety report in the "Documents" tab, if required.*