Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2022 FULL 12742

2 November 2022

Professor Stuart Dalziel

Private Bag 92019
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New Zealand

Tēnā koe Professor Dalziel

APPROVAL OF APPLICATION

Study title: PRECARE: An open-label Randomised Controlled Trial of as-needed budesonide-formoterol vs salbutamol reliever therapy in preschool children with mild asthma/recurrent wheeze

I am pleased to advise that your application was **approved** by the Northern A Health and Disability Ethics Committee (the Committee) **with non-standard conditions**. This decision was made through the FULL pathway.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee clarified that the approved use of the drug in Australia is limited and in older children for a different use than is being researched in New Zealand.
2. The Committee clarified the databases in use for recruitment would be comprised of data from Starship and other hospital admittance. The families would not know that they are on these databases but there was a large focus on ensuring the participants know where their details were collected and the use of these by named researchers solely to approach potentially eligible participants.
3. The Committee clarified that the sponsorship documents naming Professor Stuart Dalziel was necessary due to university sponsorship arrangements, and appropriate given Professor Dalziel's role with the research.
4. The Committee clarified that the dosing would be clarified with participants upon consultation with the study team to prevent daily use where not necessary.
5. The Committee clarified that there was no increased risk of any side effects on the children from the steroid use as opposed to the adult cases, that the safety in young children had been quantified and that there were no safety concerns for this age-group.
6. The Committee queried the inclusion of certain economic questions that parents would be asked. The Researcher noted that thus far in other studies collecting this information there had not yet been any notable issues raised and no pushback from parents and that this question was included for its perceived value and for the sake of consistent data across cohorts.
7. The Committee queried the accuracy of asthma diagnoses and the validity of this in the group under study, which the Researcher clarified was the reason for this study as there is a need to identify asthma in this age group.
8. The Researcher confirmed the registry the clinical trial would be registered with.

Summary of outstanding ethical issues

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please amend the statement concerning the everyday use of the drug to state that this should only be done where directed by the research team.
2. Please remove the tick-box for the option of informing a General Practitioner (GP) as this is mandatory.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern A Health and Disability Ethics Committee is required.

Standard conditions:

- Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
- Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a registry approved by the World Health Organization (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au or https://clinicaltrials.gov/).

- Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Ethics RM. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

- please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDECs.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through the Ethics Review Manager. Please clearly identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see paragraphs 125 and 126 of the *Standard Operating Procedures for Health and Disability Ethics Committees (SOPs)*.

After HDEC review

Please refer to the *SOPs* for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 02 November 2023.

Participant access to compensation

The Northern A Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialed. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation.

Further information and assistance

Please contact the HDECs Secretariat at hdecs@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information, as well as our General FAQ and Ethics RM user manual.

Nāku noa, nā

Ms Catherine Garvey

Chair

Northern A Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix B: statement of compliance and list of members

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Investigator's Brochure	Vannair_Medsafe_Med_Info		N/A
Scientific Peer Review	PRECARE HRC result	04/06/2021	1
CV for Coordinating Investigator	CV Stuart Dalziel 30062022	30/06/2022	1
Covering Letter	HDEC_covering_letter_PRECARE_28.9.22	28/09/2022	
PIS/CF	PRECARE_PIS-CF_Version_1.0_29.9.22	29/09/2022	1.0
Data Management Plan	PRECARE_Data_Management_Plan_Version_1.0_29.9.22	29/09/2022	1.0
Other	PRECARE_Hospital_ED_letter_Version_1.0_29.9.22	29/09/2022	1.0
Other	PRECARE_GP_Mail_out_Letter_Version_1.0_29.9.22	29/09/2022	1.0
Other	PRECARE_GP_Correspondence_Version_1.0_29.9.22	29/09/2022	1.0
Protocol	PRECARE_Protocol_Version_1.0_29.9.22	29/09/2022	1.0

Appendix B: Statement of compliance and list of members

Statement of compliance

The Northern A Health and Disability Ethics Committee

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Ms Catherine Garvey (Lay (the law)), Dr Kate Parker (Non-lay (observational studies)), Dr Sotera Catapang (Non-lay (observational studies)), Mr Johnathan Darby (Lay (the law/ethical reasoning)), Dr Leonie Walker (Lay (ethical/moral reasoning)), Ms Jade Scott (Non-lay (observational/intervention studies)), Dr Andrea Forde (Non-lay (intervention studies)), Mr Derek Chang (Non-lay (intervention studies)).

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference).

http://www.ethics.health.govt.nz