ST JOHN OF GOD Health Care

Human Research Ethics Committee

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15 August 2022

Dr Edward Fysh
SJG Midland Public & Private Hospitals
PO Box 1254
MIDLAND WA 6936

Dear Dr Fysh,

Re: (POPIT) A double-blind, placebo controlled randomised study to assess the tolerability, safety, and preliminary efficacy of taurolidine-citrate lock solution (TauroLock™) in patients with recurrent pleural effusions requiring management with Indwelling Pleural Catheters for recurrent effusion drainage *(Our ref: 1971)*

Thank you for the email replies of 12 August 2022, addressing the queries raised by the St John of God Health Care (SJGHC) Human Research Ethics Committee ("the Committee"), and attaching the amended Participant Information and Consent Form (PICF). Your replies have been reviewed out of session and the Committee is satisfied that there are no outstanding issues.

I am pleased to confirm ethical approval of your study as satisfying the ethical requirements under the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) ("the National Statement").

The study approval period is from 15 August 2022 to 29 February 2024. Should an extension of this timeframe be required, you must seek continued approval from the Committee before the expiry of this time period.

In accordance with NHMRC guidelines, the Participating Site/ Principal Investigator is responsible for:

1. Notification to the HREC of any adverse events or unexpected outcomes that may affect the continuing ethical acceptability of the study;
2. The submission of any proposed amendments to the study or previously-approved documents;
3. The submission of an annual progress report for the duration of the study which is due on the anniversary of HREC approval;
4. Reporting of all protocol deviations to the sponsor (if applicable) and all serious breaches reported to the HREC (preferably via the sponsor), together with details of the procedure(s) put in place to ensure the deviation or serious breach does not recur;
5. Notification and reason for ceasing the study prior to its expected date of completion (if applicable);
6. The submission of a final report and translation of results (including publications) upon completion of the study.

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The following documents have been reviewed and approved:

Title	Version	Date
Protocol	2.0	11/07/2022
Taurolock Protocol for instillation to IPC	1	11/07/2022
PICF	2	12/08/2022
Visit Sheet	1	11/07/2022
Follow up Appt	1	11/07/2022
Database for CRT	1	11/07/2022
POPIT Screening Eligibility	1	11/07/2022
ARTG Taurolock Classic		

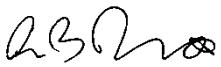
You are reminded that this letter constitutes ethical approval only. You must not commence this research at SJGHC until separate authorisation in writing has been obtained.

As per section 3.1.7 of the National Statement, you are required to register your clinical trial with a public registry before recruitment of the first participant. Please advise the SJGHC Ethics Office of the name of the registry and the trial registration number when this is known if you have not done so already.

Final approval for this study to be conducted at St John of God Midland Public and Private Hospitals is subject to receipt of a completed Participating Site Operational Approval (PSOA) form, and confirmation of approval by SJGHC Legal Services. Once this has been received by the SJGHC Ethics Office, you will be advised of final study approval in writing.

I wish you well with your research.

Yours sincerely,



Clinical Professor Dr Simon Dimmitt
Chairman
St John of God Health Care Human Research Ethics Committee

cc. Dr Charlotte Wigston, SJG Midland Hospitals
cc. Dr Anthony Bell, SJG Midland Hospital;
cc. Midland Research Office, SJG Midland Hospitals