Health and Disability Ethics Committees
Ministry of Health
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SCIENTIFIC PEER REVIEW:

Date 24/12/21

Research Title: Intraosseous Regional Administration of Diclofenac (IRAD) in Primary TKA Study: A Prospective, Double-Blinded, Randomised Controlled Trial Comparing the Analgesic Efficacy of Intraosseous Regional Diclofenac and Intravenous Diclofenac for Postoperative Pain Management in Total Knee Arthroplasty

Co-coordinating Investigator: Mr Simon W Young

Peer Reviewer Name: Dr Michal Kluger

Peer Reviewer Position: Consultant Anaesthetist

Independent from study? Yes

Peer Reviewer signature [check attached pictures below]

Recommendation: Approve

REVIEW GUIDELINE	GUIDELINE PROMPTS	COMMENTS
Relative merit of the research	• Important, worthwhile and justifiable. • Addresses a health issue that is important for health and/or society. • Aims, research questions and hypotheses build on and address gaps in existing knowledge.	The search for more effective pain relief following Total Knee Arthroplasty (TKA) is ongoing. With TKA often being associated with significant pain, minimising this leads to improved patient recovery and outcomes. Intraosseous regional administration of analgesia is a novel technique which has seen anecdotal evidence for improved postoperative pain management on our own shores as well as overseas, however there is no published evidence as of yet. This study builds on existing knowledge of intraosseous regional administration and its potential applications, which is a growing area in orthopaedic surgery. The coordinating investigator has already published papers demonstrating the benefits of using this technique in administering antibiotics for prophylaxis in TKA. These same benefits are now being applied to help reduce postoperative pain following TKA.
Design and methods	• Quality of study design • Robustness of the methods used.	The study protocol design and methods used are robust with a clear goal in mind. Sample recruitment appears

	● Includes a description of sample recruitment and characteristics (including number, gender and ethnicity where relevant) proposed methods of data analysis. ● Timelines for the research included	simple and straightforward. Methods to be used for data analysis have been clearly set out and are sound. The proposed timeline is realistic and should be achievable.
Feasibility of the research	● Overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project. ● Likely to improve scientific knowledge, concepts, technical capacity or methods in the research field, or of contributing to better treatments, services, health outcomes or preventive interventions. ● Achievable within the specified timeframe ● Researcher/research team has the appropriate experience and expertise.	The overall strategy and plan for analysis is well described and reasonable. I do not see issues with the methodology and believe the research should be achievable within the specific timeline. No published studies have investigated the efficacy of intraosseous regional analgesia in TKA. This study may represent an important milestone in providing better pain relief and outcomes for patients, and possibly lead to changes in routine practice. Findings from this study will be anticipated by the knee arthroplasty community. This research group is internationally recognised and have conducted/are currently working on multiple RCT and research projects
Reviewer Independence /objectivity	● Peer review is considered free of bias, equitable and fair. ● Objectivity can be compromised if peer reviewers have conflicts of interest, and so appropriate peer reviewers typically will not be materially connected to the researcher(s) in a way that might undermine objectivity, and be free from either positive or negative inducements. ● If the peer reviewer is connected to the study please explain what measures are taken to mitigate conflict of interest.	I have no conflict of interest and I am not involved or connected to this study.
Other comments	● Any reviewer observations that are not covered in the points above.	None

Waitemata
District Health Board

Best Care for Everyone

8th June 2021

To whom it may concern

I have been requested by the research team to offer a peer-review of the Intraosseous Regional Administration of Diclofenac (IRAD) in Primary Total Knee Arthroplasty Study.

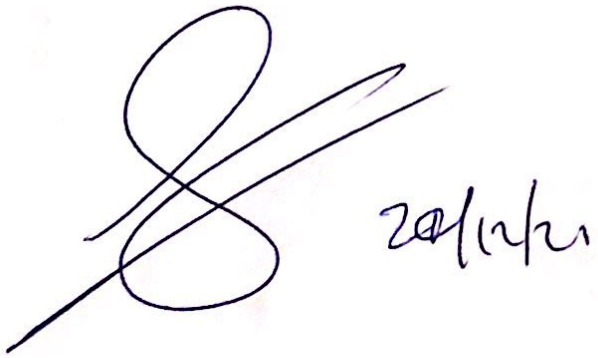
I have reviewed the protocol and study and believe that the proposed study is important, worthwhile and justifiable.

The study design and methods are robust and the overall strategy and analyses are well reasoned, appropriate and the research should be achievable within the specified timeline.

The study will also be reviewed clinically and scientifically by Southern Cross Healthcare research staff and senior management staff following ethics approval.

Both myself and the department support the application for successful HDEC ethical review.

Yours faithfully,



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Co-coordinating Investigator: Mr Simon W Young

Peer Reviewer Name: Dr Michal Kluger

Peer Reviewer Position: Consultant Anaesthetist

Independent from study? Yes

Peer Reviewer signature Michal T. Kluger

Recommendation: Approve / Revise minor / Revise major / Decline

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Relative merit of the research	• Important, worthwhile and justifiable. • Addresses a health issue that is important for health and/or society. • Aims, research questions and hypotheses build on and address gaps in existing knowledge.	The search for more effective pain relief following Total Knee Arthroplasty (TKA) is ongoing. With TKA often being associated with significant pain, minimising this leads to improved patient recovery and outcomes. Intraosseous regional administration of analgesia is a novel technique which has seen anecdotal evidence for improved postoperative pain management on our own shores as well as overseas, however there is no published evidence as of yet. This study builds on existing knowledge of intraosseous regional administration and its potential applications, which is a growing area in orthopaedic surgery. The coordinating investigator has already published papers demonstrating the benefits of using this technique in administering antibiotics for prophylaxis in TKA. These same benefits are now being applied to help reduce postoperative pain following TKA.
Design and methods	• Quality of study design • Robustness of the methods used. • Includes a description of sample recruitment and characteristics (including number, gender and ethnicity where relevant) proposed methods of data analysis. • Timelines for the research included	The study protocol design and methods used are robust with a clear goal in mind. Sample recruitment appears simple and straightforward. Methods to be used for data analysis have been clearly set out and are sound. The proposed timeline is realistic and should be achievable.
Feasibility of the research	• Overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project.	The overall strategy and plan for analysis is well described and reasonable. I do not see issues with the methodology and believe the research should be achievable within the specific timeline.