WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Dr Michael Smyth
University of Warwick
Warwick Cliical Trails Unit
University of Warwick
Gibbet Hill Campus
Coventry
CV4 7AL

West of Scotland REC 1
West of Scotland Research Ethics Service
Ward 11
Dykebar Hospital
Grahamston Road
Paisley PA2 7DE
www.nhsggc.org.uk
Date 01 September 2020
Please note: This is the date the letter was released by the REC but will not necessarily be the date of final issue.
Direct line 0141-314-0212
e-mail WosRec1@ggc.scot.nhs.uk

Dear Dr Smyth

Study title:	**Paramedic Analgesia Comparing Ketamine and MorphiNe in trauma**
REC reference:	**20/WS/0126**
Protocol number:	**SOC.12/19-20**
EudraCT number:	**2020-000154-10**
IRAS project ID:	**1003404**

The Research Ethics Committee reviewed the above application at the meeting held on 01 September 2020.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC Sites

The favourable opinion applies to all NHS sites listed in the application taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland)being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Cover Letter [PACKMaN Initial Submission Cover Letter]	1.0	17 August 2020
EudraCT PDF [EudraCT Form]	1.0	17 August 2020
Financial Arrangements [Funding Letter]	1.0	07 August 2019
Investigator Brochure/SmPC [Ketamine SMPC]	1.0	26 June 2020
Investigator Brochure/SmPC [Morphine SMPC]	1.0	26 June 2020
Miscellaneous [3 Month CSRI Questionnaire]	1.0	17 August 2020
Miscellaneous [Sponsorship Approval Letter]	1.0	17 July 2020
Miscellaneous [6 Month CSRI Questionnaire]	1.0	17 August 2020
Miscellaneous [EQ-5D-5L]	1.0	17 August 2020
Miscellaneous [Trial Data Flow Diagram]	1.0	27 July 2020
Miscellaneous [BPI-SF Questionnaire]	1.0	17 August 2020
Miscellaneous [Electronic Prompts for Questionnaires]	1.0	17 August 2020
Miscellaneous [ED Information Leaflet]	1.0	17 August 2020
Miscellaneous [Questionnaire Cover Letter]	1.0	17 August 2020
Miscellaneous [GP Letter]	1.0	17 August 2020
Miscellaneous [CWoW ethical considerations form]	1.0	18 August 2020

Document	*Version*	*Date*
Miscellaneous [Payment of compensation to participants]	1.0	18 August 2020
Participant information and informed consent form [Patient Information Leaflet]	1.0	17 August 2020
Participant information and informed consent form [Brief Information Leaflet for Paramedics]	1.0	17 August 2020
Participant information and informed consent form [Cover Letter for Legal Representative]	1.0	17 August 2020
Participant information and informed consent form [Consent Form for Legal Representative]	1.0	17 August 2020
Participant information and informed consent form [Reminder Cover Letter Legal Representative]	1.0	17 August 2020
Participant information and informed consent form [Patient Consent Form]	1.0	17 August 2020
Participant information and informed consent form [Reminder Invite Letter]	1.0	17 August 2020
Participant information and informed consent form [Invite Letter]	1.0	17 August 2020
Proof of Insurance [Insurance]	1.0	24 June 2020
Protocol [PACKMaN Protocol]	1.0	17 August 2020
Recruitment Arrangements [Recruitment and informed consent procedure]	1.0	18 August 2020
Suitability of the investigator/Investigator CV [Prof Perkins CV]	1.0	11 February 2019
Suitability of the investigator/Investigator CV [Dr Smyth CV]	1.0	26 November 2018

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

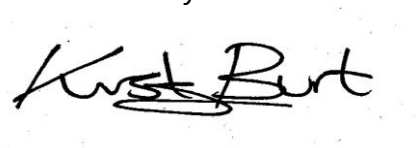
HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 1003404 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely



On behalf of
Dr Malcolm Booth
Chair

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments
	"After ethical review – guidance for researchers"
Copy to:	Mrs Jane Prewett, University of Warwick Lead Nation

West of Scotland REC 1

Attendance at Committee meeting on 01 September 2020

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Malcolm Booth	Consultant in Anaesthesia and Intensive Care (Chair)	Yes	Chair of Meeting
Dr Katriona Brooksbank	Clinical Trial Manager (Vice Chair)	No	
Miss Clodagh Duffy	Pre-Registration Clinical Scientist	No	
Dr Ross Fairgrieve	Consultant in Paediatric Anaesthesia and Pain Management	No	
Dr Natasha Fullerton	Consultant Neuroradiologist	No	
Mrs Elspeth Fulton	Retired Senior Clinical Research Associate (CRA)	No	
Miss Linda Galbraith	Former Management Consultant	Yes	
Mrs Lynda Hamilton	Retired Manager	Yes	
Dr Peter Hutchison	GP	Yes	
Miss Gemma Kaur	Clinical Pharmacist	Yes	
Mrs Katharine Kilgour	Registered Physiotherapist	Yes	
Dr Derek Manson-Smith	Information Research Consultant (Retired)	Yes	
Dr John D McClure	Statistician	Yes	
Mrs Laura Rooney	CRUK Lead Research Nurse	Yes	
Dr Patricia Roxburgh	Medical Oncologist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Veronika Burgess	Assistant Coordinator
Mrs Kirsty Burt	Senior Co-ordinator
Dr Judith Godden	Scientific Officer
Dr Joe Hawkins	Observer