National Research Ethics Committee

NREC-MD Meeting Minutes

17 October 2024

Attendance

Name	Role
Prof. Barry O'Sullivan (Chair)	Chair, NREC-MD
Prof. Mary Sharp (Deputy Chair)	Deputy Chair, NREC-MD
Dr Caitriona Cahir	Member, NREC-MD
Dr Mireille Crampe	Member, NREC-MD
Dr Ruth Davis	Member, NREC-MD
Dr Owen Doody	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Dr James Gilroy	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Mr Billy McCann (PPI)	Member, NREC-MD
Prof. Tom Melvin	Member, NREC-MD
Prof. Therese Murphy	Member, NREC-MD
Dr Declan O'Callaghan	Member, NREC-MD
Dr Clare O'Connor	Member, NREC-MD

Dr Paul O'Connor	Member, NREC-MD
Dr Joanne O'Dwyer	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Dr Louise Houston	Project Officer, National Office for Research Ethics Committees
Dr Sarah McLoughlin	Programme Officer, National Office for Research Ethics Committees
Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees

Apologies: Prof. Declan Patton (Deputy Chair), Dr Daniel Coakley, Dr Gloria Kirwan, Prof. Cara Martin, Prof. Mahendra Varma, Mr Peter Woulfe, Ms Simone Walsh

Quorum for decisions: Yes

Agenda

1. Welcome (Chairperson)
2. Report on Committee business
3. Minutes of previous meeting
4. Declarations of interest
5. 24-NREC-MD-022-R1
6. 24-NREC-MD-026
7. 24-NREC-MD-027
8. 23-NREC-MD-036-SM1
9. AOB

- Prof. Barry O'Sullivan welcomed the Committee and acknowledged apologies sent and opened the meeting.
- Declarations of interest:
  - Mr Damien Owens (24-NREC-MD-022-R1) did not read the documentation associated with the application and vacated the meeting while the study was under discussion.

Applications

24-NREC-MD-022-R1

- Principal Investigator (Lead institution): Prof Andrew Sharp (Mater Hospital)
- Study title: SPYRAL AFFIRM Global Clinical Study of Renal Denervation with the Symplicity Spyral Renal Denervation System in Subjects with Uncontrolled Hypertension (SPYRAL AFFIRM)
- Sponsor: Medtronic
- NREC-MD Decision
  - *Favourable with Conditions*
- Associated conditions
  - Future use of data: The NREC-MD note the proposed changes to the PIL/ ICF are technically compliant with GDPR. As the role of NRECs is to promote best practice we ask that further consideration is given to the consent for future use to give participants greater freedom to exercise their rights regarding future use of their data. Future research involving participant data from current study is subject to separate Research Ethics Committee review.
  - Exposure to ionising radiation: The NREC-MD request that Section O of the NREC-MD application form is updated in line with the response to request to further information.
  - The HTN - Hypertension Health survey: In line with best practice, the Committee request a consideration is given to revising the survey items by minimising leading questions. Furthermore, the Committee request that upon data collection completion the tool's validity and reliability are analysed and reported in all publications.

24-NREC-MD-026

- Principal Investigator (Lead institution): Prof. Faisal Sharif (University Hospital Galway)
- Study title: A Pivotal, Prospective, Multicenter, 2:1 Randomized, Double Blind, Controlled, Study Comparing the THerapeutic IntravasculaR Ultrasound (TIVUS™) REnal Denervation System vs. Sham for the Adjunctive Treatment of Hypertension (The THRIVE Study)
- Sponsor: SoniVie, Ltd.
- NREC-MD decision:
  - *Request for further information*
- Further Information Requested:

- The NREC-MD raised a number of queries in relation to the proposed study design. The Committee note that the comparator of the study is a sham procedure, and that all participants will be required to stop their hypertension medication for minimum 2 months. With this in mind, please provide justification for the study design.
- The NREC-MD note that the participants and all study personnel taking follow-up blood pressure measurements will be blinded to the randomization up to 6 months post-randomization. Please clarify whether and how the study will be blinded at the point of device administration, i.e. will the PI be performing the procedures for all participants, including the sham group and how this impacts the blinded study.
- The NREC-MD note that all participants, including those in the sham group, will undergo radiological imaging as part of the procedure, exposing those in the sham group to unnecessary radiation. Please clarify:
- If the participants in the sham group must undergo radiological imaging or if sham imaging without radiation is possible.
- If there is any radiological exposure that is additional to standard of care for all participants.
- As the application documentation states that “Travel expenses may be reimbursed by the sponsor upon submission of the relevant receipts “, the NREC-MD request that participants will be reimbursed for all reasonable expenses.
- Given the substantial commitment required on the study participants to comply with all study procedures, the NREC-MD request due consideration is given to whether participants should be compensated for lost income for their time on the study. Please review the EUREC statement on compensation of research participants for more information.
- The NREC-MD note that while that the PIL is comprehensive, the information on what is involved in participation in the sham group is not presented in a clear and accessible way. The committee requests that the PIL clearly outlines the procedures, changes to medications and risks involved in each group in the first pages of the document.
- Furthermore, the Committee request that the term ‘sham treatment’ is revised to ‘sham procedures’ for clarity throughout the PIL/ICF
- The NREC-MD request that the risks of withdrawing hypertension medication are clearly outlined in the PIL, especially as the study population is routinely reminded by health care professionals of the importance of hypertension medication adherence.
- As per point 5b above, if all participants will undergo extra radiation, the section on risks of radiation on page 18 must be revised to clearly state this.
- The PIL states that only those at the site will have access to personal data, however medical records will be accessible outside of the site on an online platform for 72 hours. Please clearly state and explain this in the PIL.

- The PIL page 16 and 23 states that the participants ‘cannot be identified from coded data’. As this statement is inaccurate, the Committee request this statement is revised.
- The PIL page19 states ‘Your doctor has decided that the procedure you are undergoing is required due to your clinical condition’. This statement implies that the doctor has decided that participation in the study is required for the participant’s health, which is not the case. Participation in a study is voluntary. The Committee request that this statement is rephrased.
- The reference to approval by a ‘federal authority’ on page 2 should be removed as it is not applicable.
- The NREC-MD noted that page 9 states that the device is inserted into renal arteries ‘through the vagina located in the groin’ and requests this is revised for accuracy.
- The NREC-MD note that the indemnity & insurance arrangements is extensive and confusing and the procedures put a lot of onus on the participant, eg to report any damage to health to insurers within a 7 day window. The Committee requests the section on insurance is revised.
- Further to point 17, the Committee request justification for this 7 day time window and clarity on the implications of reporting within this time period on indemnity.
- The NREC-MD request a separate consent for data to be sent outside of the EU is included in the ICF.
- The NREC-MD note that the recruitment materials state ‘FDA approved’ and request these are revised as this information is not relevant and potentially misleading to participants in Ireland
- The NREC-MD note that the recruitment materials use the term ‘struggling with hypertension’ and query whether
- This might affect the recruitment strategy as individuals who currently manage their hypertension with medication may not identify with the add.
- The wording raises expectation that the study will help participants with struggles to control hypertension. Given the investigational nature of the device, the Committee requests that this is revised.
- The NREC-MD note that the sponsor is awaiting feedback from the participating sites DPO. Include any further feedback / engagement if available when responding to this request for further information.

24-NREC-MD-027

- Principal Investigator (Lead institution): Prof Gerard O'Sullivan (University Hospital Galway)
- Study title: Single arm, Multicenter, Prospective Registry Investigating Efficacy and Safety of Mechanical Thrombectomy (JETi®) in Acute and Acute-on-Chronic Arterial Occlusions in Femoropopliteal and Proximal BTK-Lesions (JETART)

- Sponsor: Vascular Science LP GmbH
- NREC-MD Decision
  - *Request for further information*
- Further information requested:
  - Section O(6) of the NREC-MD application form references the use of angiographic imaging. Please confirm whether this or any other study procedures involve exposure to ionising radiation? If yes, Section O of the application form should be completed and reference to the use of radiation is to be included in the participant information leaflet / informed consent form (PIL/ICF).
  - Section T of the NREC-MD application form should be updated to ensure all declarations have been read and agreed to (boxes ticked).
  - A declaration of interest form should be provided from the Principal Investigator.
  - The NREC-MD note the potential risk of a perforation or dissection of the blood vessel at the time of procedure. Please outline what actions are in place to mitigate risks that may occur during the procedure and update the study documentation accordingly.
  - The NREC-MD note that individuals will potentially be recruited and consented by a person with a previous clinical relationship. The Committee request that this activity be assigned to an authorised designee of the Principal Investigator (as per ISO 14155:2020), who is a member of the investigating team appropriately qualified under national law (as per Article 63(2)(c) of the In Vitro Medical Device Regulation (EU) 2017/746) to minimise any perception of coercion.
  - The NREC-MD note that participants with childbearing potential that do not use adequate contraceptive methods will be excluded from this study. Please clarify whether the device is CE marked for use in individuals of childbearing potential or whether this exclusion is specific to this clinical investigation. If specific to this clinical investigation, provide justification for this.
  - The NREC-MD request that:
  - Contact details for the lead Principal Investigator in Ireland are moved to page 1 of the PIL alongside the contact details of the sponsor contact details in Germany.
  - The risks/ adverse events of participation in the study are quantified/ categorised based on risk and likelihood of occurrence.
  - The PIL/ICF is updated to note that iD3 Medical will keep pseudonymised data for five years following study completion.
  - The section in the PIL titled “What if something goes wrong?” is revised and simplified to ensure clarity and accessibility.
  - The DPO communication states that a company called Euroimage Research will be responsible for analysing pseudonymised ultrasound and angiographic images. However, there is no references to this in either the NREC-MD application form or the

PIL/ICF. Update the application form and PIL/ICF accordingly or clarify this discrepancy.

- It is currently unclear from the information provided where and for how long imaging data will be retained / stored for. Confirm and update the application form and PIL/ICF accordingly.
- The NREC-MD note that the sponsor is awaiting feedback from the participating sites DPO. Include any further feedback / engagement if available when responding to this request for further information

23-NREC-MD-036-SM1

- Principal Investigator (Lead institution): Prof. Faisal Sharif (University Hospital Galway)
- Study title: Distal Evaluation of Functional performance with Intravascular sensors to assess the Narrowing Effect: Guided Physiologic Stenting (DEFINE GPS)
- Sponsor: Philips Medical Systems
- NREC-MD Decision
  - *Favourable*

AOB

- The Chairperson thanked the Committee and closed the meeting.