FAQs

Inclusion/ Exclusion Criteria

1. **Can a patient take part in the study if they are already on amlodipine?**
   No.

2. **Can a patient take part in the study if they are already taking a calcium channel blocker (CCB)?**
   Yes, if the patient stops taking the CCB medication for 3 months or changes to an alternative anti-hypertensive.

3. **What is the definition of Moderate/severe heart disease or severe hepatic disease?**
   This is based on the opinion of the local PI.

4. **Can a patient be rescreened if they do not initially meet the inclusion criteria?**
   Yes.

5. **Are patients with pacemakers ineligible?**
   Yes, as a pacemaker precludes a patient from undergoing a CT or MRI scan, the patient would be ineligible for the study. Any condition which precludes a patient from required scanning at the baseline and 52 week visit would render the patient ineligible.

6. **If a patient is on memantine or a cholinesterase inhibitor how long will it take for a decision about their eligibility to be made?**
   If a patient is taking memantine or a cholinesterase inhibitor the Cholinesterase Inhibitor & Memantine referral form is required to be completed and forwarded to the NICTU who will forward this to the Diagnostic Monitoring and Event Adjudication Committee. The committee will have 5 days to submit a response to the NICTU which will then be forwarded to the site.

Informed Consent

1. **Can a research nurse gain consent from a patient?**
   The PI is ultimately responsible for gaining consent; however the PI can designate this to another person which can be a research nurse. The designated person should be documented on the delegation log.

2. **Do patients need to have the capacity to consent for themselves?**
   Yes, patients need to be able to consent themselves. Inclusion criteria no. 4 states that patients must have a sMMSE score between 15 and 26 (inclusive), therefore patients will have the capacity to consent themselves.

3. **If the patient loses capacity during the trial are they able to carry on with the study?**
   Yes, if patients lose capacity during the study they can still carry on with the study as they consented to take part in the study at the start.

4. **If the patient is unable to write how is the consent form completed and signed?**
   The clinical trial regulations allow for the patient to give their consent orally in the presence of at least one witness who must sign the consent form as evidence that the information was accurately explained and understood by the patient and that consent was freely given.
   As the informant is involved in the conduct of the trial they cannot act as the witness. An impartial third party should witness the entire consent process and sign the consent document.

Clinical Procedures

1. **Is it possible to carry out home visits for patients?**
   Yes, this is possible if bloods and ECG tests can be carried out at the home visit. If a patient is seen in the home then all subsequent visits should be carried out in the home.

2. **Will sites be provided with study equipment including ECGs, BP monitors etc.?**
   Sites will be supplied with a VADAS-cog testing kit, all other equipment will need to be sourced at a site level.

3. **Will ECGs be read locally or centrally?**
   ECGs are to be read locally at each site.

4. **Is there a definition for cortical function, moderate/ severe heart disease or hepatic disease?**
   No, there will be no additional definitions only the result codes; normal, not clinically significant, clinically significant and not done should be used. Where there is uncertainty this will be decided locally by the PI.

Cognitive Assessments & Questionnaires

1. **Who can administer the cognitive assessment and questionnaires?**
   Any member of the study team who has been fully trained and the training log completed can carry out the assessments.

2. **Are any of the assessments blinded?**
   Yes, the CGIC is a blinded assessment. Therefore the CGIC rater can only administer the CGIC and no other assessments or study duties.

3. **Can a research nurse administer the CGIC assessment?**
   Yes, any member of the study team that has been trained on the CGIC assessment can administer the CGIC.

4. **Should the CGIC be performed on the informant or the patient first?**
   The CGIC must be carried out on the informant before the patient. This allows an accurate assessment to be obtained from the carer before assessing the patient.

5. **Will a stop watch or timing device be supplied with the VADAS-cog kit for timed assessments?**
   No, a stop watch or timing device will not be supplied. A more subtle approach to timing should be adopted to prevent distress to the patient while under assessment or a distraction. Please use a watch, phone or wall clock when performing the assessments.

MRI Procedure

1. **Does the study have particular MRI specifications?**
   Yes, this information can be found in the Imaging Guideline & Procedures which is supplied in the Trial Manual.

2. **Are sites required to perform local phantom MRI scans?**
   No, local phantom MRI scans are not required.

3. **The protocol asks for "lesion quantification." How should this be completed?**
   The review of MRI images/ lesion quantification will be completed centrally by the AFFECT Imaging Co-ordinating Centre at King's College Hospital. The MRI images should be burnt onto a CDR and sent to the AFFECT Imaging Co-ordinating Centre. The Imaging Guideline & Procedures can be found in the trial manual.

Study Database/ CRF

1. **Is it possible for the PI to use an electronic signature on SAE reports?**
   No, electronic signatures are not permitted. If the PI is off-site, the report should be forwarded to them to obtain an original signature.
   The partially completed form should be submitted to the NICTU within 1 working day by email and the fully completed/ signed form should be reported within 3 working days.

2. **If a patient is successfully randomised and recorded onto the screening database, will this patient be pre-populated in the clinical database?**
   No, both the screening and clinical databases sit separately. When a patient has been successfully randomised they must then be manually activated within the clinical database and all detail recorded accordingly.

3. **How are on-going pre-randomisation medications managed?**
   All on-going medications recorded on the Pre-Randomisation Form must also be recorded in the Current Mediations Form and managed while the patient is enrolled in the study.

EMERGENCY UNBLINDING

1. **What is the arrangement for Out of Hours Code Breaking?**

   The Out of Hours Code Breaking/ Emergency Unblinding will be facilitated via the online randomisation service for the study, Sortition. The unblinding Username and Password is in a sealed envelope within the ISF and also the Pharmacy File.

MISCELLANEOUS

1. **Is it possible for patients to have a 'drug holiday'?**

   Yes it is acceptable for patients to stop taking the study medication for a few weeks. This should be documented as it will effect overall drug compliance.