TARDIS – Working Practice Document – No: 027

Title: Trial Steering Committee

The role of the Trial Steering Committee (TSC) is to provide overall supervision of the trial. It should also provide advice, through its independent Chairman, to the Chief Investigator (CI), the British Heart Foundation (BHF) and the Host Institution (University of Nottingham) on all aspects of the trial. The TSC will include independent members who are not directly involved in other aspects of the trial; this will provide protection for trial participants, the CI, funder and sponsor.

A) Terms of reference

1. To monitor and supervise the progress of the TARDIS trial towards its interim and overall objectives;
2. To review at regular intervals relevant information from other sources (e.g. other relevant trials)
3. To consider the recommendations of the Data Monitoring and Ethics Committee;
4. In the light of 1,2 & 3, to inform the BHF on the progress of the trial;
5. To advise the BHF on publicity and the presentation of all aspects of the trial.

B) Membership

Membership should be limited and include an independent Chairman, the CI and grant applicants, and two other independent members, trial statistician and a lay/consumer representative. Statisticians etc should attend meetings as appropriate. Observers will include the Trial Co-ordinator, and representatives from the BHF and Host Institution.

Independent Chairman, Helen Rodgers (Newcastle)
Chief Investigator, Philip Bath (Nottingham)
Hugh Markus (London)
Tom Robinson (Leicester)
Graham Venables (Sheffield)
Stan Heptinstall (Nottingham)

Independent Experts:

Ahamad Hassan (Leeds)

William Toff (Leicester)

Patient Representative, Oswald Newell (Nottingham)

BHF, Funding Representative – to be advised

University of Nottingham Observer, Angela Shone

C) Guidance Notes

i) Meetings

The TSC should meet at least annually although there may be periods when more frequent meetings are required; they may be called by the CI or Chairman of TSC. Responsibility for and organising the meetings lies with the CI and Trial Co-ordinator. Paper for meetings should be circulated ***two weeks*** in advance and accurate minutes should be prepared by the Trial Co-ordinator on behalf of the CI and agreed by all other members.

A quorum will consist of 5 members:– Independent Chair, Chief Investigator (or nominated representative), 1 Independent Expert, 1 Co-Investigator and 1 other member.

A copy of the minutes should be sent to BHF.

ii) Management

The role of the TSC is to provide overall supervision of the trial and ensure that it is conducted to rigorous ethical and research governance standards. In particular, the TSC should concentrate on progress of the trial, adherence to protocol, patient safety and the consideration of new information. Day to day management of the trial is the responsibility of the Trial Management Committee.

Patient Safety

In all TSC deliberations, the rights, safety and well being of the trial participants are the most important considerations and should prevail over the interests of science and society. The TSC should ensure that the protocol demands freely given informed consent from every trial participant. The TSC should look closely at the patient information provided and advise the investigators on its completeness and suitability.

iii) Progress of the Trial

It is the role of the TSC to monitor the progress of the trial and to maximize the chances of completing it within the time scale agreed by the BHF.

The CI must send a brief progress report to BHF annually (on the anniversary of the grant). The reports will be endorsed by the TSC and should be stand alone, and inform the BHF of any new information that has a bearing on safety or ethical acceptability of the trial, or any significant complaints arising, with a justification of any decisions taken on the matter. The TSC should act as arbitrator in cases of participant grievances. A final report (endorsed by the Head of Department) is required within 3 months of the end of the grant.

iv) Adherence to Protocol

The TSC should ensure there are no major deviations from the trial protocol. If the CI needs to make any material changes to the protocol during the course of the trial, approval should be sought from the TSC, MREC, MHRA and BHF as funder.

v) Consideration of New Information

The TSC should consider new information relevant to the trial including reports from the DMEC and the results of other studies. It is the responsibility of the CI and the TSC Chairman and independent members of the TSC to bring to the attention of TSC any results from other studies of which they are aware that may have a direct bearing on future conduct of the trial.
On consideration of this information, the TSC should recommend appropriate action, such as changes to trial protocol, additional patient information or stopping or extending the study. The rights, safety and well being of the trial participants (present and future) should be the most important considerations in these deliberations.

The TSC should advise on dissemination of results and findings of the trial.

It is the responsibility of the investigators to report regularly the extent of serious adverse events to the TSC and DMEC. In the case of unexpected SAE's, the regulatory authority and the Chairman of the TSC should be notified.

Data Monitoring and Ethics Committee

The TSC should, at its first meeting, establish a Data Monitoring and Ethics committee (DMEC) that meets regularly to view the data and the results of any interim analyses. The terms of reference and guidelines for DMECs are covered in the DMEC WPD and charter. DMEC members should be independent of both the trial and TSC.

The TSC should receive open minutes of DMEC meetings and their recommendations about continuation of the trial.

D) Contact details

Helen Rodgers
Clinical Professor of Stroke Care/
Deputy Director of Stroke Research Network
Institute of Health & Society
4th Floor William Leech Building
The Medical School, University of Newcastle
Newcastle Upon Tyne NE2 4HH
Tel: 0191 222 8025
Email: helen.rodgers@ncl.ac.uk

Philip Bath
Stroke Association Professor of Stroke Medicine
Division of Stroke Medicine, Clinical Sciences Building
Nottingham University Hospital NHS Trust
Hucknall Road, Nottingham NG5 1PB
Tel: 0115 823 1768
Email: philip.bath@nottingham.ac.uk

Hugh Markus
Professor of Neurology
St George's University of London
Cranmer Terrace, London
SW17 ORE
Tel: 0208 7252735
Email: hmarkus@sgul.ac.uk

Tom Robinson
Dept of Cardiovascular Sciences
University Hospitals of Leicester
UHL NHS Trust, Gwendolen Rd
Leicester LE4 4PW
Tel: 0116 258 4081
Email: tgr2@le.ac.uk

Graham Venables
Consultant Neurologist and Clinical Director
Central Sheffield University Hospitals Trust
Neurology Dept
Sheffield Royal Hampshire Hospital
Sheffield, S10 2JF
Tel: 0114 271 2197
Email: Graham.Venables@sth.nhs.uk

Stan Heptinstall
Division of Cardiovascular Medicine
School of Clinical Sciences
Queen's Medical Centre
Nottingham NG7 2UH
Tel: 0115 8231013
Email: s.heptinstall@nottingham.ac.uk

Ahamad Hassan
Consultant Neurologist and Stroke Physician
Dept of Neurology
Leeds General Infirmary
Great George St
Leeds LS1 3EX
Tel: 0113 392 3258
Email: Ahamad.hassan@leedsth.nhs.uk

William D Toff
Senior Lecturer in Cardiology, Dept of Cardiovascular Sciences
Director, Leicester Clinical Trials Unit
Dept of Health Sciences
University of Leicester
Clinical Science Wing
Glenfield Hospital, Groby Rd
Leicester LE3 9QP
Tel: 0116 250 2500
Email: w.toff@le.ac.uk

Oswald Newell
The Coach House
6 Mevell Court
Clumber Road East
The Park
Nottingham NG7 1BD
Tel: 0115 912 1450
Email: oswald.newell@ntlworld.com

BHF - Funding Representative – to be advised

Angela Shone
Research Governance Manager
Research Innovation Services
University of Nottingham
King's Meadow Campus
Lenton Lane
Nottingham NG7 2NR
Tel: 0115 8467906
Email: Angela.shone@nottingham.ac.uk

E) Version control

Version 1.0, April 2009

Version 1.1, July 2009

Version 1.2, October 2010

Version 1.3, January 2011

F) Agreement

I agree to be a member of the Trial Steering Committee for the above trial and to fulfil the roles and responsibilities of such membership as detailed above. As a member of the TSC I can confirm that:

- I have no scientific or ethical objections to the trial objectives and design
- I have no direct involvement in the trial
- I will keep all data and results from the trial confidential
- I have no conflict of interest

Name:

Signature:

Date: