Supplementary File 3 Organisational structure and responsibilities

Principal Investigator and Research Physician
Design and conduct of the CATERPILLAR-study
Preparation of protocol and revisions
Preparation of the case report forms
Organising steering committee meetings
Organising data safety monitoring board meetings
Publication of study reports
Data verification
Screens and recruits study subjects
Obtains Informed Consent
Confirms eligibility
Randomisation
Responsible for trial master file
Makes study related medical decisions
Assesses (serious) adverse device events
Reports (serious) adverse device events

Steering committee (members described on title page of protocol)
Agreement of final protocol
All lead investigators will be steering committee members. Recruitment of patients and liasing with principle investigator
Reviewing progress of study and if necessary agreeing changes to the protocol to facilitate the smooth running of the study.

Trial manager
Study planning
Organisation of steering committee meetings
Provide annual ethics committee report
Advice for lead investigators
Assistance with international review, board/independent ethics committee applications

Data Managers
Entry/correction of data in case report forms in Castor
Resolves data queries
Maintains essential documents
Data verification

Research Nurses
Prepares medical device administrations
Obtains Informed Consent
Stores medical device