

Supplement 1 Composition and responsibilities of the principal investigator, steering committee, trial management committee, and data management team overseeing the trial

Principal investigator and research physician

Design and conduct of BEAHIT

Preparation of protocol and revisions

Preparation of investigators brochure and CRFs (case report forms)

Organising steering committee meetings

Managing clinical trials office

Publication of study reports

Steering committee (see title page for members)

Agreement of final protocol

All lead investigators will be steering committee members.

Recruitment of patients and liaising with principle investigator

Reviewing progress of study and if necessary agreeing changes to the protocol

Trial management committee

Study planning

Organisation of steering committee meetings

Provide annual risk report and ethics committee

Responsible for trial master file

Budget administration and contractual issues

Advice for lead investigators

Assistance with international review, board/independent ethics committee applications

Organisation of central serum sample collection

Data Monitoring Committee

Audit of feedback forms at each visit and decide when a site visit to occur

Review the accumulating data and determine if a trial should be modified or discontinued

Audit the completeness and overall quality of the data, interview coordinators and investigators, examine the source documents, and check that the center has complied with the protocol verification

Audit AE

Statistics Research Section of second military medical university

Randomization

Statistical analysis

Lead investigators

Lead investigator MCL, WY and ZGR will be in charge of identification, recruitment, data collection and completion of CRFs, along with follow-up of study patients and adherence to study protocol and investigators brochure.
