STUDY INFORMATION

Sample size	225
Participating countries	Spain, The Netherlands
No. sites in SPAIN	6: Hospital Clínic, Doce de Octubre, La Princesa, Germans Trias i Pujol, Miquel Sevet, Hospital de Bellvitge.
No. sites in The Netherlands	1: Radboudumc
Participating sites	32 (competitive recruitment)
Recruitment period	36 months
Follow-up period	12 months
Overall duration (including submission + conduction + close-out)	5 years
No. monitoring visits	1 SIV + 1MV + 1 COV per site
Medical Device	Suction-irrigation vibration device
Regulatory status	CE marked for the intended purpose

TASKS LIST

Trial design and protocol procedures
Sample size, statistical design
Write and review statistical sections of the protocol
eCRF & Data Management (DM)
eCRF Definition
Data Management Plan (DMP) and Data Validation Plan
Build eCRF, annotated CRF, program and validate checks
Training to investigators/monitors
Code data AE
Data base maintenance and quality control
Close Database and provide Final Data Management Report
SAEs Reconciliation
Only listings + External Manual checking
Data transfer (DT) to Statistical data
Programming of DT
Quality control of data transfer
Blind Data Review (BDR)
Prepare deviations criteria for DBR
Prepare BDR listings and BDR report
Declaration of the different data subsets for analysis
Statistical Analysis Plan (SAP)
Issue SAP and list of tables, listings and graphs
Randomization
Prepare randomization codes
Prepare MACRO for randomization
Data and Safety Monitoring Board (DSMB)
Statistical Analysis Plan for DSMB
Statistical Programming, Analysis/es and Reports
Statistical programming
Statistical programming and documenting
Issue programming report
Results and Statistical report
Statistical Results
Write draft and final statistical report (Introduction, Methods, Results)
Quality control on the statistical report