KOORDINATIONSZENTRUM
FÜR KLINISCHE STUDIEN
MEDIZINISCHE UNIVERSITÄT WIEN

Premature termination of a Clinical Trial

Full title of the clinical Trial: Dabigatran as an alternative anticoagulant in patients with left ventricular assist device

Pilot-Trial: Dabigatran as an alternative anticoagulant in patients with left ventricular assist device

EudraCT Number: 2010-024534-38

Sponsor: Medical University of Vienna

Represented by (name): Dr. med. univ. Roxana Moayedifar

Reason for premature termination of the clinical trial:

Thromboembolic events in the study medication group led to early termination of this randomized controlled trial of Dabigatran versus Phenprocoumon in LVAD patients.

Study results (if available):

The study was stopped prematurely for safety reasons after 16 patients (61±8 years, 1 female) were randomized. Thromboembolic events occurred in 4 subjects receiving dabigatran (50%) and in 1 receiving phenprocoumon (13%; P=0.28). No major bleeding was recorded, and no patient died during the study. Median time to treatment termination was significantly shorter in dabigatran patients (8.5 versus 12.0 months; P=0.015).

Date and Signature of Sponsor representative: 11.11.2020