

Bilaga 1 Clinical endpoint of the COTTIS 1 clinical study

Primary clinical endpoint:

The time to reach the target temperature of 35°C (oesophageal) and safety and feasibility of treatment and protocol.

Secondary clinical endpoints

Infarction volume performed in the standard CT 24 hours after thrombectomy,

Change/increase of the infarct nucleus based on imaging at the time of admission and CT after 24 hours

Re-canalisation result (by TICI score) after thrombectomy and 24 hours after thrombectomy

NIHSS upon admission, upon discharge/transfer to rehabilitation

mRS 0 – 2 upon discharge/transfer in rehabilitation

mRS 0 – 2 after 3 months (read hard endpoint in the pivotal trial)

Proportion of patients with very good clinical outcome after 3 months (mRS 0-1)

Mortality during acute hospitalisation and after 3 months

Temperature curve at various measuring locations (oesophageal, tympanic)

Safety endpoints

Occurrence of intra cerebral haemorrhage

Any ICB on the progression CT after 24 hours

Symptomatic ICB (defined according to SITS-MOST criteria):

ICB >30% of initial infarction volume associated with a clinical deterioration in NIHSS score of at least 4 points within 24 hours