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# O-038 - A SAFETY AND EFFICACY STUDY OF NICAPLANT® IN ANEURYSMAL SUBARACHNOID HAEMORRHAGE PATIENTS UNDERGOING ANEURYSM CLIPPING

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## Resumen

**Introduction:** Aneurysmal subarachnoid hemorrhage (SAH) has high morbidity and mortality. Secondary mechanisms of injury can aggravate the high negative impact. Cerebral vasospasm (CV) is one of the most relevant causes of this secondary injury. To improve the current limitation of treatment options, NicaPlant® was developed.

**Objectives:** This phase 2b study aimed to assess the efficacy of local nicardipine application via controlled release polymers NicaPlant® on the incidence of moderate to severe CV following SAH.

**Methods:** The trial was performed as an international randomized, controlled, single-blinded multicenter study. 40 Patients with WFNS grade 3 and 4 SAH undergoing surgical repair of their ruptured aneurysm were randomized to receive ten pellets of NicaPlant® (40 mg) plus standard of care or standard of care alone. The implants were administered immediately following clip ligation of the ruptured aneurysm in proximity to all the exposed cerebral blood vessels. The primary endpoint was the incidence of moderate to severe CV (day 8 ± 1). A blinded independent outcome accessor analyzed all imaging data.

**Results:** In the implant group, 20% (4/20) of patients reached the primary endpoint, compared to 58% (11/19) of patients in the control group (p = 0.024). Including mild CV, 75% of all patients in the control group developed CV compared to 30% in the implant group (p = 0.0129). 32% (6/19) of the patients in the control group developed new cerebral infarction, compared to 10% (2/20) in the implant group (p = 0.1273). Endovascular rescue therapy was performed in 10% of the patients in the implant group compared to 58% in the control group (p = 0.002). 4 subjects (20%) in the control group experienced Treatment-emergent adverse events (TEAE), compared with none in the active group.

**Conclusions:** In this prospective randomized multicenter Phase 2b trial, we could demonstrate the safety and efficacy of NicaPlant® implants in preventing CV in patients with SAH.