Early Closure of the SWEET ACS Study

(Intensified Multifactorial Intervention on Hyperglicemic Patients with Acute Coronary Syndromes)

Sponsor: Heart Care Foundation ONLUS, Florence, Italy

EudraCT number	Sponsor code	Title
2007-000543-98	G110	SWEET-ACS Intensified Multifactorial Intervention on Hyperglicemic Patients with Acute Coronary Syndromes

Trial Summary

The SWEET-ACS study was a prospective, multicenter, national, randomized, open-label trial whose main objective was to evaluate whether intensive treatment of hyperglycemia and other traditional risk factors could improve prognosis in patients admitted to ICU for acute coronary syndrome (ACS) and hyperglycemia at entry (glycaemia between ≥140mg/dl and <200mg/dl), regardless of the presence of diabetes mellitus. The study also aimed to evaluate whether glucose intolerance (defined as altered fasting glycemia or glucose intolerance) diagnosed during hospitalization has a negative prognostic impact in patients with ACS.

The randomized study was accompanied by an observational study aimed to assess the degree of application of the guidelines and the 2-year outcomes of patients with ACS and glycemia ≥200 mg/dl at the time of admission.

The study protocol planned to randomize 1500 patients with ACS and hyperglycemia (plasma glucose between ≥140 mg/dl and <200mg/dl at the time of admission) in a period of 18 months by 100 Italian ICUs. Patients with ACS and hyperglycemia (plasma glucose between ≥140 mg/dl and <200mg/dl at the time of admission) were randomized to an intensive multifactorial treatment or to the usual care. All randomized patients had to be followed up at 30 days and 4 months after enrollment. Thereafter, patients randomized to intensive treatment were reviewed in follow-up every 4 months while those randomized to conventional treatment were reviewed in follow-up every 8 months. The expected mean follow-up for this event driven study was 2 years with a minimum follow-up of one year. The observational study in patients with ACS and glycemia ≥200 mg/dl had only one follow-up at 24 months.

The first patient was randomized in June 2007.

From the beginning, the trend of enrollment by the activated centers has been very slow and only 20 of the 48 activated sites enrolled patients. After about 12 months from study start, only 70 patients had been randomized even if various strategies have been adopted from the Coordinating Center and the Steering Committee to understand the reasons for insufficient recruitment and to encourage greater participation of the centers.

Insufficient patient recruitment led the Steering Committee to make the decision to terminate the study early despite the significant scientific interest on the project. The reasons for this low recruitment were several:

- type of patient to be included in the randomized study was found to be less frequent than estimated based on the analysis of the literature;

- complexity of the study itself which required the collaboration of various specialist figures;
- coordination of the entire team following the patient;
- complex and short-term follow-up.

The early termination of the study took place on July 11, 2008.

The enrolled patients were all informed of the early interruption of the study and were followed up according to the procedures of good clinical practice in full compliance with the ACS guidelines.

The Investigators and the IRBs were informed of the early closure of the study.

Due to the small number of enrolled patients, data were not sufficient to achieve the main objective of the study.