Kantonsspital St.Gallen

RELAX - RLX030A

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A multicenter, randomized, double-blind, placebocontrolled phase III study to evaluate the efficacy, safety and tolerability of Serelaxin when added to standard therapy in acute heart failure patients

The purpose of this study is to evaluate the efficacy, safety and tolerability of intravenous infusion of 30 µg/kg/day serelaxin administered by body weight category (Table 5-3) for 48 hours, when added to standard therapy, in approximately 6,375 acute heart failure (AHF) patients. Efficacy will be determined based on the relative reduction in CV death and other clinical outcomes through a follow-up period of 180 days, as compared to placebo.
The rate of mortality in AHF remains high despite contemporary standardof-care management, which has not changed significantly in the last 10 years, and represents a key unmet need for AHF patients. In the RELAX AHF trial a clinically and statistically significant 37% reduction in both CV and all-cause mortality through Day 180 were seen. Data from this study is intended to replicate the reduction in mortality in AHF patients observed in the RELAX AHF trial.

keywords	Primary objective: Evaluate the effect of serelaxin compared to standard of care in reducing in hospital WHF or all cause deaths through day 5 Endpoints: Primary endpoint: Worsening of Heart Failure (WHF) requiring rescue therapy or all cause death through 5 days
type of project	clinical studies
status	completed
start of project	2014
Swissmedic notification number	2014DR3033
responsible person	Dr. med. Micha Mäder