

# Investigational Plan

## Screening and Randomization: All Groups

### 1. Screening:

Medical history

Physical Examination

ECG, Routine Blood sampling +

Troponin

**Check of Inclusion / Exclusion  
Criteria**

Screening-Log

#### **Inclusion Criteria:**

Admission to the Emergency Department with symptoms consistent with ACS:

- Typical chest pain (with or without ECG-changes)

suggestive of unstable angina or non-ST-elevated myocardial infarction (NSTEMI)

-Troponin I negative at admission

-Patient willing and able to give written informed consent

#### **Exclusion Criteria:**

Patients with ST-elevation myocardial infarction (STEMI)

Continuing chest pain or recurrent episodes of chest pain

Patients who need to be hospitalized for other medical reasons

Patients in need of urgent life-saving interventions such as cardiogenic shock and acute heart failure

Patients under 18 years of age

Patients with a life expectancy < 6 months

Patients with any condition that leads the treating physician to not consider the patient eligible for the trial

TnT Result neg.



Informed Consent

Supplementary request for Copetin test

Randomization

Experimental  
Group

Control  
Group

Release of Copeptin result for  
experimental group only

**Investigational Plan**  
**Experimental Group**

**Randomization into  
experimental group**

**Request of Copeptin result from central  
laboratory with randomization code**

**Copetin at admission  
positive**

**Copetin at admission  
negative**

**Standard  
management**

Physical examination, ECG  
AE/SAE Assessment  
Patient satisfaction survey

SAE Assessment until  
discharge  
Patient satisfaction survey at  
discharge from ED / CPU

**Discharge**  
into ambulant care via praxis  
connect

Investigational Plan  
Control group

**Randomization into  
control group**

Copeptin results will not be  
revealed to treating physicians

Standard management

SAE Assessment until  
discharge  
Patient satisfaction survey at  
discharge from ED / CPU

# Investigational Plan

Follow-up: All groups

**Telephone contact:  
Follow up 30 days**

Assessment of survival  
Assessment for AEs and SAEs

**Telephone contact:  
Follow up 90 days**

Assessment of survival  
Assessment for AEs and SAEs