

Management of the patient with heart failure and diabetes: may insulin be a problem?

200 patients ≥ 70 year-old with HF and T2DM

Clinical and instrumental evaluation according to guidelines + NT-proBNP monitoring

Insulin

Observational cohort
N=50

No-insulin

N=150

Need for insulin
therapy²

No-insulin
N=50

Insulin withdrawal¹

RANDOMIZATION

Insulin
N=50

**Empaglifozin/
liraglutide**
N=50

- self-monitoring of blood glucose and BW;
- Clinical follow-up and ECG every 6 months. with HbA1c, NT-proBNP³, microalbuminuria;
- Echocardiographic exam at 1 year of follow-up and end of study.

Primary endpoint combination⁴ of blood glucose variability, HbA1c, BW;
Secondary endpoints: NT-proBNP, microalbuminuria and clinical events.

1: pts will be identified according to (1) clinical criteria for a safe withdrawal, (2) informed consent of the individual pt, (3) number of pts needed;

2: expected incidence should be $\geq 5\%$ /year, according to administrative data (Regione Puglia) and to trial data (SUSTAIN-6, LEADER trials);

3: NT-proBNP measured in local clinical chemistry laboratories;

4: details on construction of primary endpoint will be provided in the study protocol.