ESC23 Late-Breaker Discussion

The STEP HFpEF Trial

Randomized | Parallel Assignment

Study aim:

This study will look at how the participants daily life is affected by their heart failure. The study will also look at the change in participants body weight from the start to the end of the study. This is to compare the effect on heart failure symptoms and on body weight in people taking semaglutide (a new medicine) to people taking "dummy" medicine.

Condition

Obesity

Intervention/Treatment

Drug: Semaglutide

Drug: Placebo (semaglutide)

Inclusion Criteria

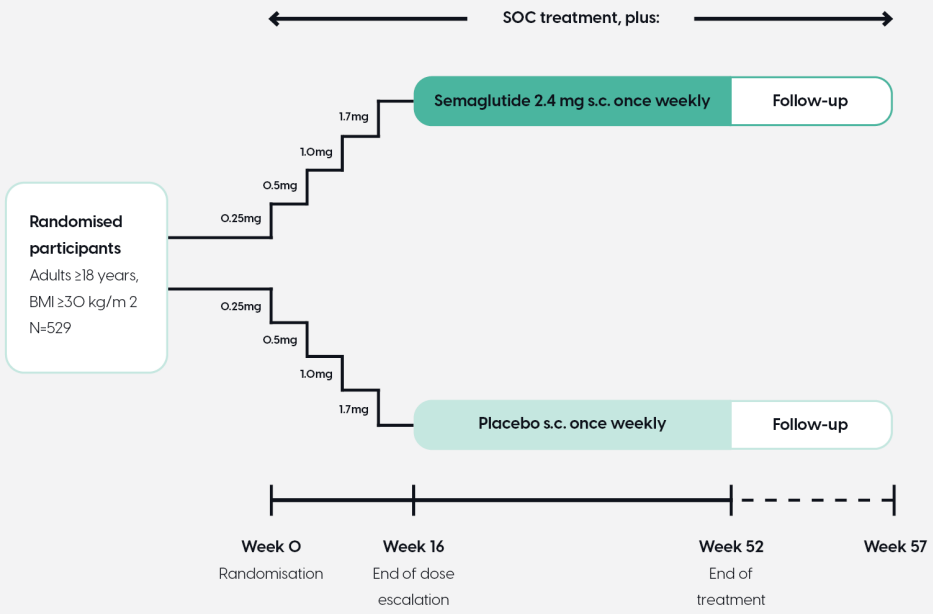
LVEF ≥45%, NYHA functional class II IV, KCCQ CSS <90 points, 6MWD ≥100 metres, and ≥1 of the following:

- Elevated left ventricular filling pressures (invasively measured)
- Elevated natriuretic peptide levels and structural echocardiographic abnormalities
- HF hospitalisation (previous 12 months) and ongoing requirement for diuretics and/or structural echocardiographic abnormalities

Exclusion Criteria

- Prior/planned bariatric surgery
- Recent self reported weight change >5 kg (11 lbs)
- Recent adverse CV event or HF hospitalisation
- SBP of >160 mmHg at screening
- HbA_{1c} ≥6.5% or known medical history of diabetes

STEP HFpEF trial design



Primary Endpoints

- Change in KCCQ CSS from baseline to week 52
- Percentage change in body weight from baseline to week 52

Secondary Endpoints

- Change in 6MWD from baseline to week 52
- Change in CRP from baseline to week 52

Conclusion:

Collectively, these results indicate that treatment with semaglutide is a valuable therapeutic approach in the management of patients with HFpEF and obesity. Large magnitude of benefits, clinically meaningful and highly statistically significant.

cardiology

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