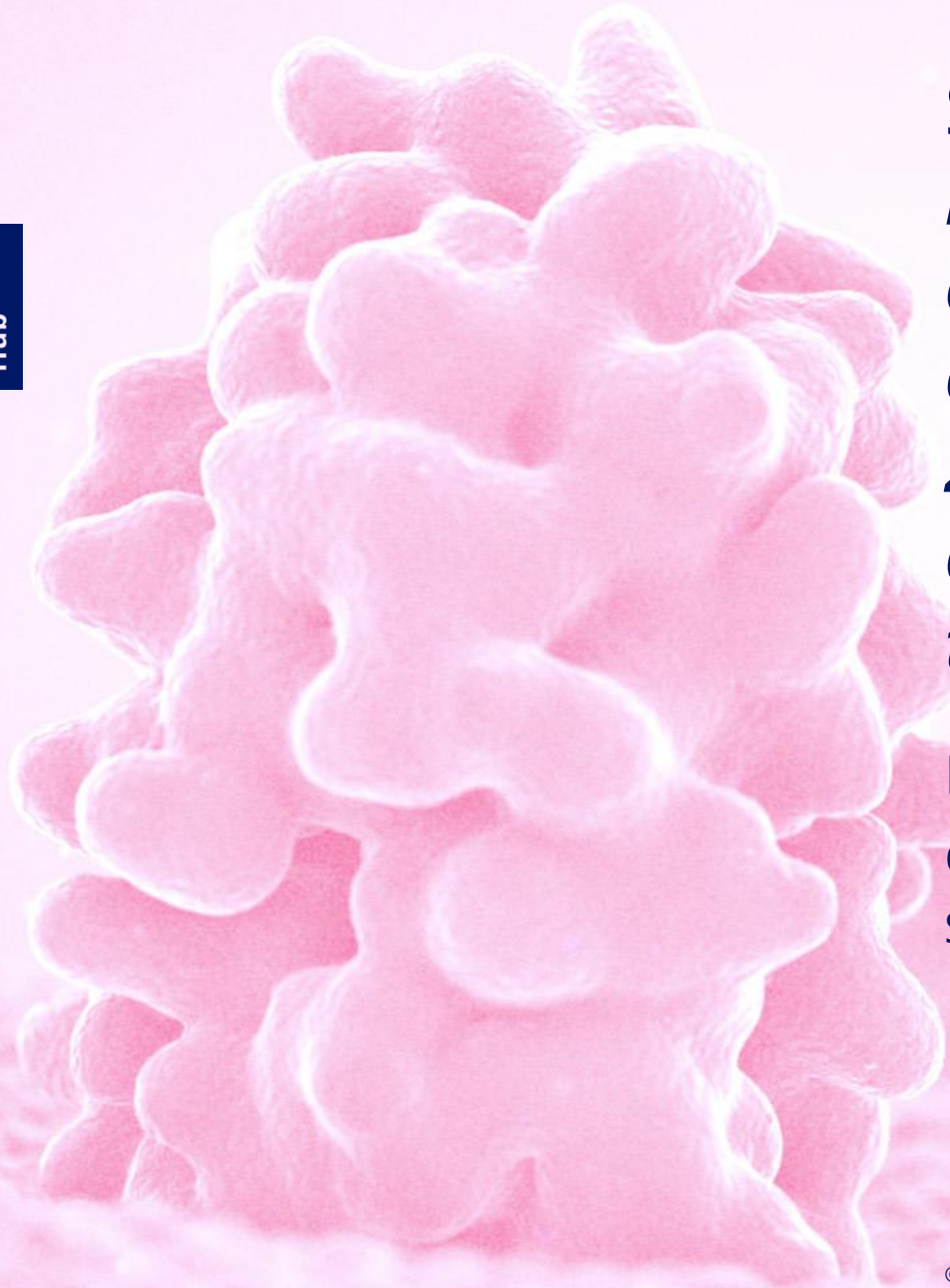
Science Hub



Synopsis of the original article

Efficacy and safety of co-administered once-weekly cagrilintide 2.4 mg with once-weekly semaglutide 2.4 mg in type 2 diabetes: a multicentre, randomised, double-blind, active-controlled, phase 2 trial

Frias JP, et al. Lancet. 2023;

doi: 10.1016/S0140-6736(23)01163-7

Synopsis created and reviewed by Novo Nordisk

Background

Science Hub

Combining the GLP-1RA semaglutide with the long-acting amylin analogue cagrilintide has weight loss benefits

The impact of combining these two drugs on HbA_{1c} is unknown

This phase 2 trial assessed the efficacy and safety of co-administered semaglutide with cagrilintide (CagriSema) in participants with T2D

GLP-1RA, glucagon-like peptide-1 receptor agonist; T2D, type 2 diabetes.

Methods

Adults with T2D

BMI ≥ 27 kg/m²

On metformin ± SGLT2i

Randomisation (1:1:1)

- OW s.c CagriSema 2.4 mg
- OW s.c semaglutide 2.4 mg and placebo
- OW s.c cagrilintide 2.4 mg and placebo

32 weeks

Primary endpoint: Change from baseline in HbA_{1c}

Efficacy analyses: In all randomised participants

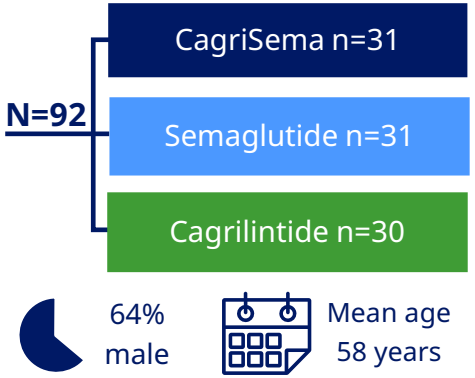
Secondary endpoints: Bodyweight, FPG, CGM parameters, AEs and hypoglycaemia

Safety analyses: In all randomised participants who received at least one dose

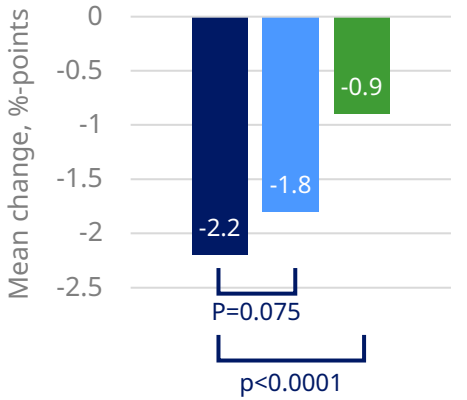
AEs, adverse events; BMI, body mass index; CGM, continuous glucose monitoring; FPG, fasting plasma glucose; SGLT2i, OW, once-weekly; s.c, subcutaneous; sodium-glucose cotransporter-2; T2D, type 2 diabetes.

Results

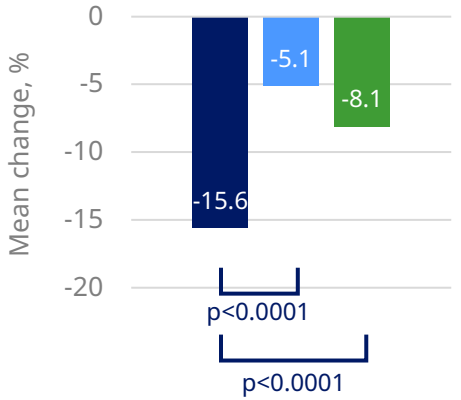
Participants



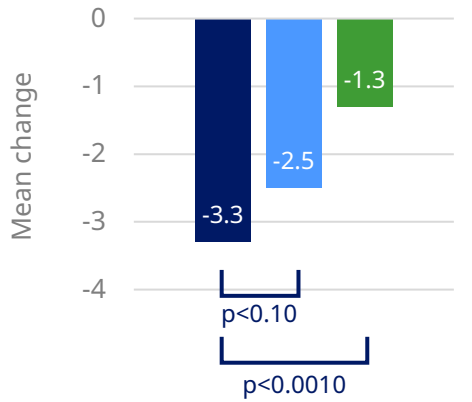
Mean change in HbA_{1c} from baseline to week 32



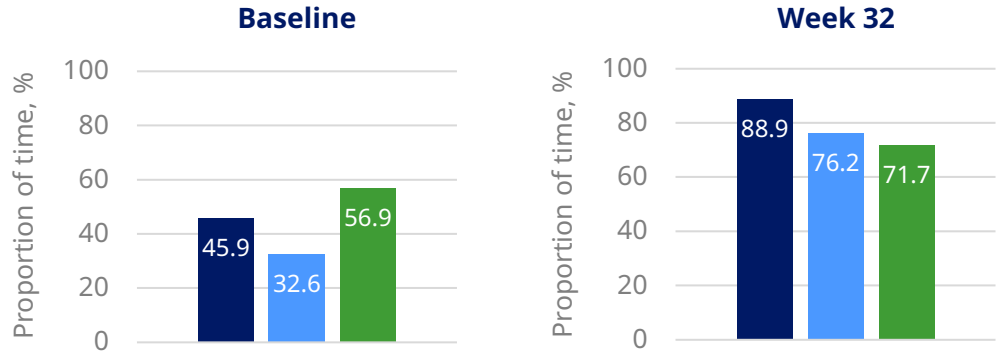
Mean change in bodyweight from baseline to week 32



Mean change in FPG from baseline to week 32

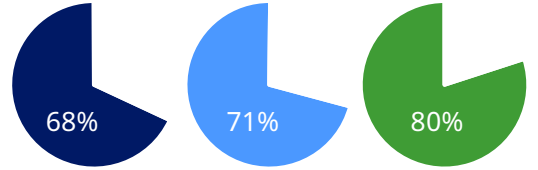


Time in range (3.9-10.0 mmol/L)



Adverse events

Participants reporting adverse events



Mild or moderate gastrointestinal adverse events were most common

No level 2 or 3 hypoglycaemia reported

No fatal adverse events were reported

CagriSema, co-administered semaglutide and cagrilintide; FPG, fasting plasma glucose.

Conclusions

In people with T2D, treatment with CagriSema resulted in clinically relevant improvements in glycaemic control (including CGM parameters). The mean change in HbA_{1c} with CagriSema was greater versus cagrilintide, but not versus semaglutide

Treatment with CagriSema results in significantly greater weight loss versus semaglutide and cagrilintide and was well tolerated

These data support further investigation of CagriSema in this population in longer and larger phase 3 studies

CagriSema, co-administered semaglutide and cagrilintide; CGM, continuous glucose monitoring; T2D, type 2 diabetes.