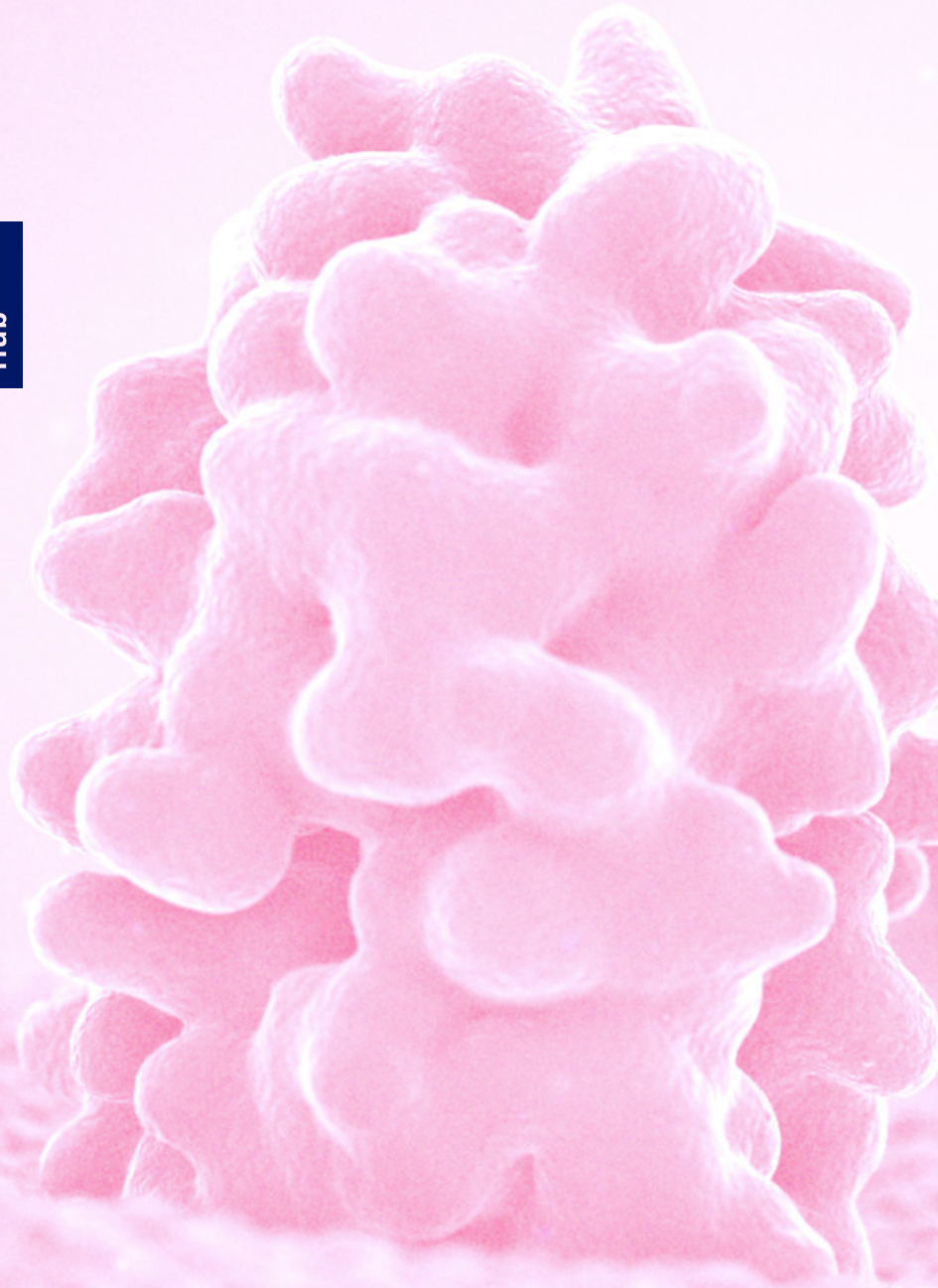
Science Hub



Synopsis of the original article

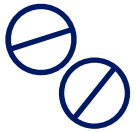
Efficacy and safety of once-daily oral semaglutide 25 mg and 50 mg compared with 14 mg in adults with type 2 diabetes (PIONEER PLUS): a multicentre, randomised, phase 3b trial

Aroda VR, et al. Lancet. 2023;
doi: 10.1016/S0140-6736(23)01127-3

Synopsis created and reviewed by Novo Nordisk

Background

Science Hub



Once-daily oral semaglutide is an effective type 2 diabetes treatment

The PIONEER PLUS trial aimed to investigate a new formulation of oral semaglutide at investigational doses of 25 mg and 50 mg versus the approved 14 mg dose in adults with inadequately controlled type 2 diabetes

SCIENCEHUB.NOVONORDISK.COM

Methods

- **Adults with T2D and HbA_{1c} 8.0–10.5%**
- **BMI ≥25.0 kg/m²**
- **Stable daily dose of 1–3 oral glucose-lowering drugs**

Randomisation (1:1:1)

- Once-daily oral semaglutide 14 mg
- Once-daily oral semaglutide 25 mg
- Once-daily oral semaglutide 50 mg

68 weeks

Primary endpoint: Change in HbA_{1c} from baseline to 52 weeks

Efficacy analyses: Evaluated with a treatment policy estimand

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

BMI, body mass index; T2D, type 2 diabetes.

Results

Participants

N=1606

- Oral semaglutide 14 mg n=536
- Oral semaglutide 25 mg n=535
- Oral semaglutide 50 mg n=535

41.7% female

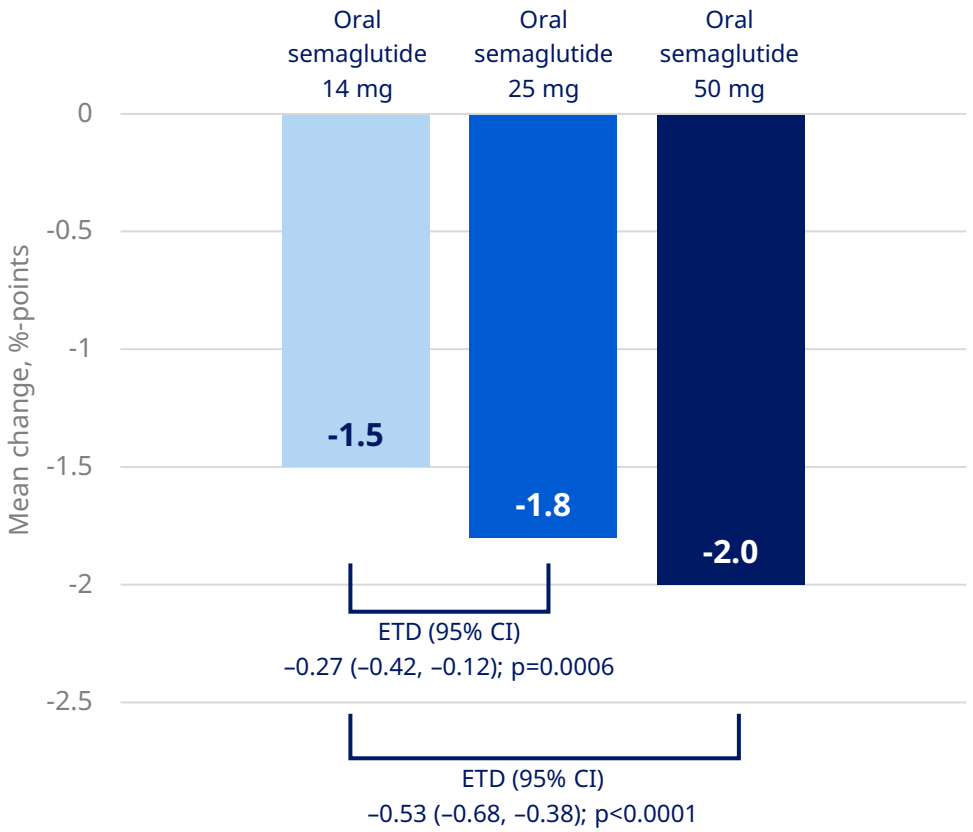
Mean age 58.2 years

Baseline characteristics

Baseline mean HbA_{1c} (SD) was 9.0% (0.8)

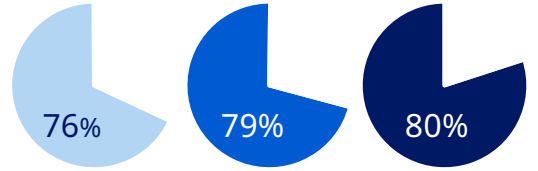
Baseline mean bodyweight (SD) was 96.4 kg (21.6)

Mean change in HbA_{1c} from baseline to week 52



Adverse events

Participants reporting adverse events



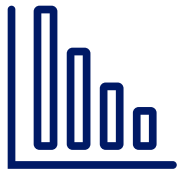
Oral semaglutide 14 mg | Oral semaglutide 25 mg | Oral semaglutide 50 mg

Gastrointestinal adverse events were more frequent with oral semaglutide 25 mg and 50 mg versus 14 mg and were mostly mild or moderate in severity

CI, confidence interval; ETD, estimated treatment difference; SD, standard deviation.

Conclusions

Science Hub



Oral semaglutide 25 mg and 50 mg were superior to 14 mg in reducing HbA_{1c} and bodyweight in adults with inadequately controlled type 2 diabetes

No new safety concerns were identified

SCIENCEHUB.NOVONORDISK.COM