Liraglutide For Weight Management in Pubertal Adolescents With Obesity: A Randomized Controlled Trial

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ORIGINAL ARTICLE

A Randomized, Controlled Trial of Liraglutide for Adolescents with Obesity

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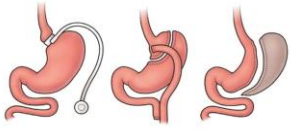
Alla typer av behandling syftar till samma sak:

Beteendestöd

Fetmakirurgi



Läkemedel

Äta mindre!

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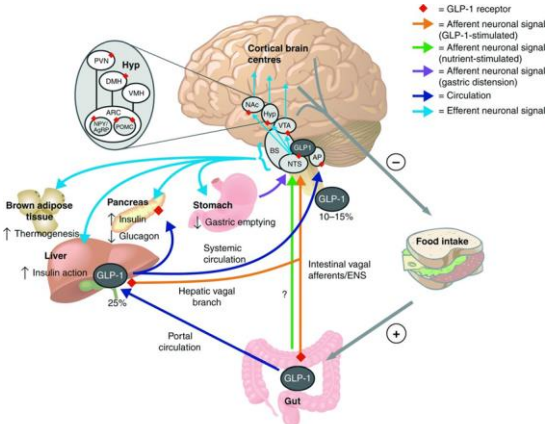
Liraglutide

- En modifierad GLP-1 molekyl med en fettsyra påsatt
- Förlängd halveringstid: 13h vs 10 minuter för GLP-1
- Säljs och är rabatterat för typ2 diabetes
- Godkänt men inte rabbaterat som Saxenda för vuxna med fetma
- Högre dos för fetma än för diabetes: 3.0mg
- Dagliga injektioner



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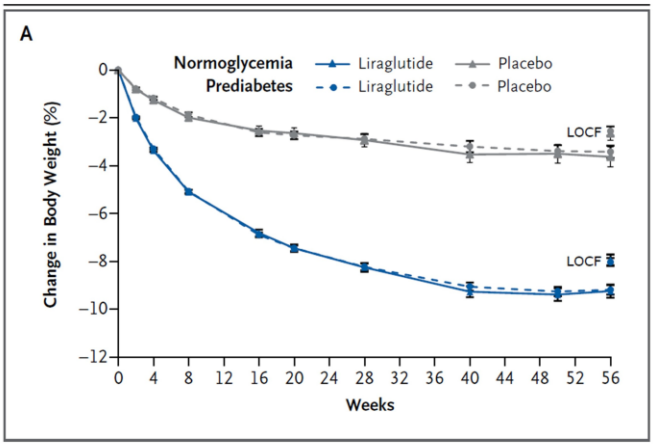
Liraglutide effects on weight loss in adults

- 20-30% are non responders
- Side effects: gastrointestinal, primarily
- Possible severe effect: pancreatitis
- Positive long-term effects on cardiovascular risks



NEJM 2015

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Trial Design

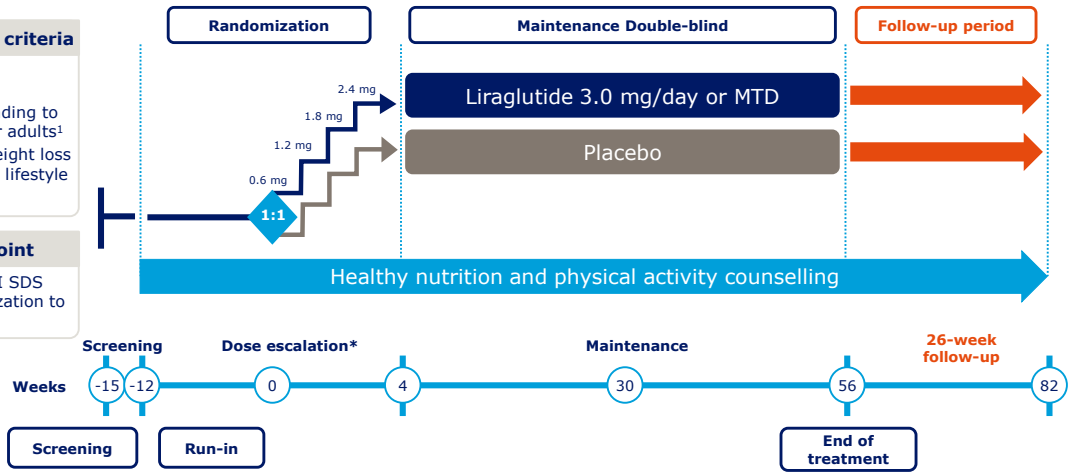
Randomized controlled, double-blind multinational study

Key eligibility criteria

- 12–<18 years (pubertal)
- BMI corresponding to ≥30 kg/m² for adults[1]
- Insufficient weight loss in response to lifestyle therapy alone

Primary endpoint

- Change in BMI SDS from randomization to 56 weeks



1. Cole TJ, et al. BMJ (Clinical research ed) 2000;320:1240–3.
Randomization was stratified by pubertal and glycemic status. Quality of life was assessed by Impact of Weight on Quality of Life [IWQOL]-Kids questionnaire.
BMI SDS, body mass index standard deviation score; MTD, maximum tolerated dose; QoL, quality of life.

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Baseline Characteristics

Sex, female 59%	Age 14.5 years	Tanner 4-5* 83%
Weight 101 kg (222 lb.)	BMI 36 kg/m²	BMI SDS 3.2
Blood pressure 117/72 mmHg	HbA_{1C} 5.3%	Dysglycemia 26%

Full analysis set: all randomized participants who received ≥1 dose of trial product and have any post-randomization data. Data are observed means or numbers [observed mean proportions], respectively.
*Overall tanner stage for each participant is calculated as maximum tanner stage combining all the categorical questions per visit.
HbA_{1c}, glycated hemoglobin

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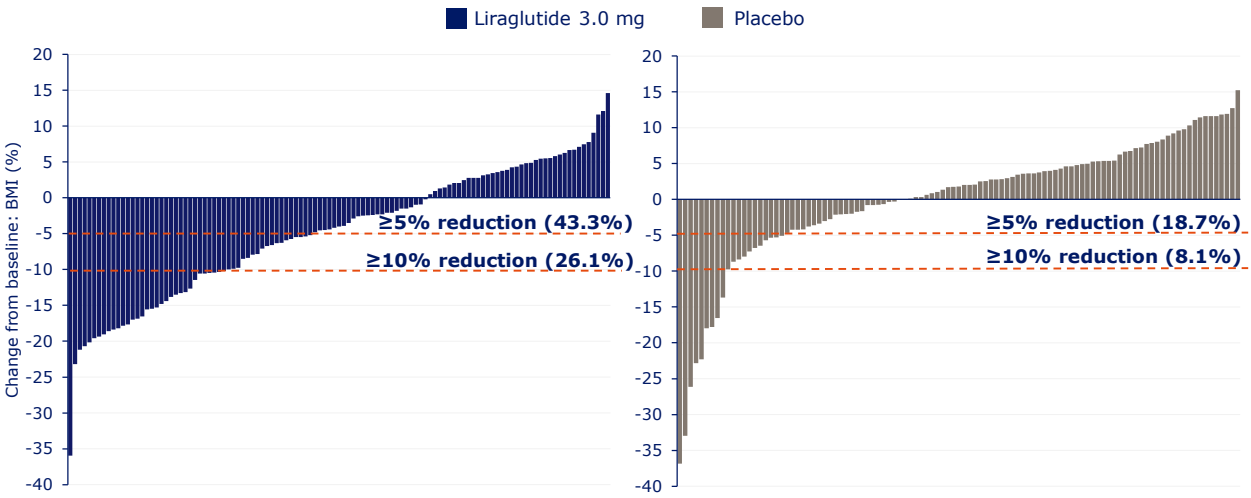
Change In BMI Percent

0–56 weeks



Full analysis set. Statistical analysis is logistic regression with jump-to-reference missing data imputation.
*post-hoc analysis

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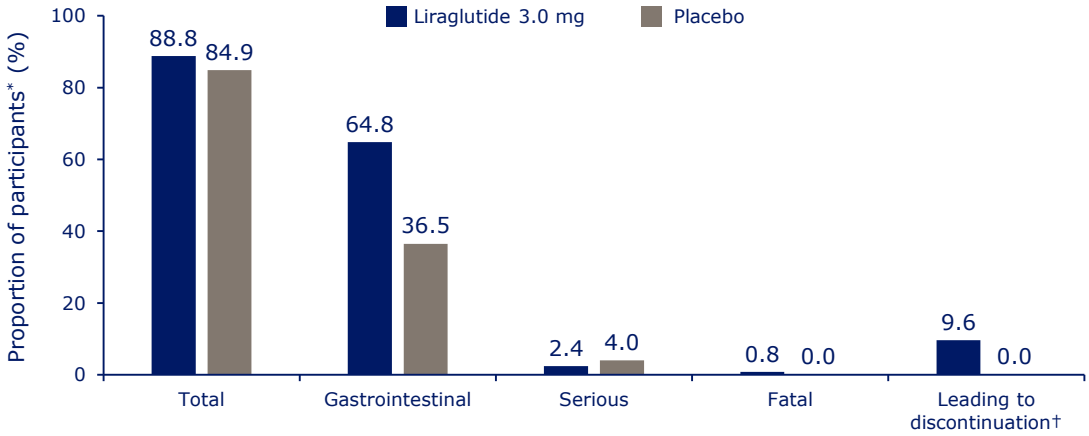
Adverse Events Overview

0–56 weeks



Safety analysis set (n=125 for liraglutide and n=126 for placebo). Data are from participants on-treatment (including events occurring up to 14 days after the last day on trial product).
*Participants experiencing at least one event.
†Leading to discontinuation of trial product

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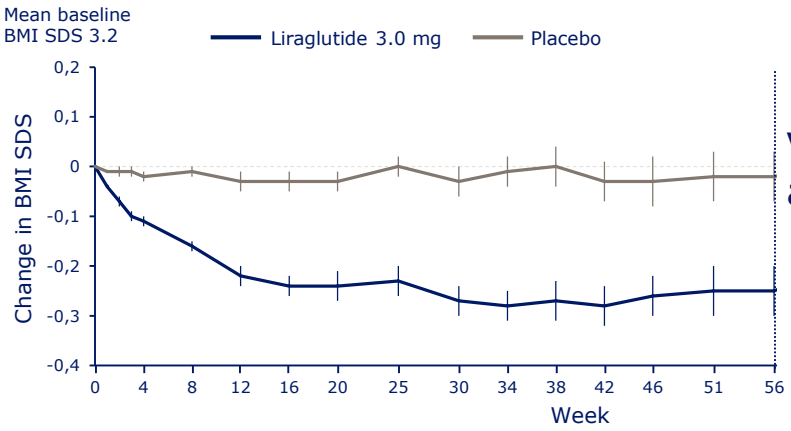
BMI SDS Over Time

0–56 weeks



Vad händer efter avslutad behandling?

Full analysis set. Graph is observed mean data ± SEM. n, number of participants included in the analysis.
CI, confidence interval; ETD, estimated treatment difference; SEM, standard error of the mean

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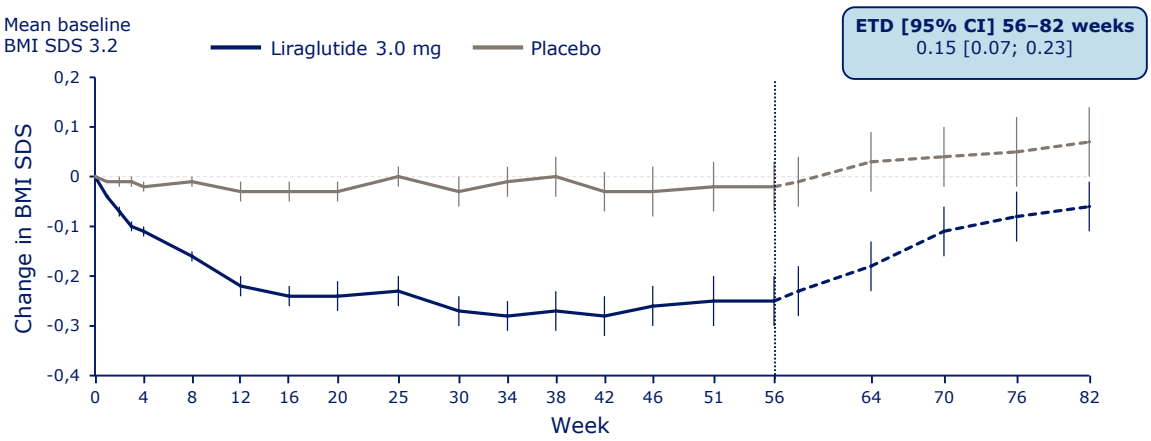
BMI SDS Over Time

0–82 weeks



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CI, confidence interval; ETD, estimated treatment difference; SEM, standard error of the mean

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Vad händer nu?

- Ansökan inskickad i både USA och EU om indikation för fetmabehandling från 13 åå
- Tveksamt om läkemedlet blir rabatterat..

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Thank you