

From the LDC Writing Group: **Congratulations** to **Melanie** on her international article, heading a team of writers on behalf of colleagues from France, Germany, Spain, Israel, South Africa, Spain, Sweden, the UK and the USA, published in the August issue of the high-impact journal, **JAMA (Journal of the American Medical Association)**, Volume 314, Issue 7, pages 687-699. The SCALE trial to test how effective liraglutide is for weight loss was conducted in 71 study centres.



Efficacy of Liraglutide for Weight Loss Among



Patients With Type 2 Diabetes: The SCALE Diabetes Randomized Clinical Trial

Melanie J. Davies, MD¹; Richard Bergenstal², MD; Bruce Bode, MD³; Robert F. Kushner, MD⁴; Andrew Lewin, MD⁵;
Trine Vang Skjøth, MD⁶; Arne Haahr Andreasen, MSc⁶; Christine Bjorn Jensen, MD⁶;
Ralph A. DeFronzo, MD⁷;
for the NN8022-1922 Study Group

¹Diabetes Research Centre, University of Leicester, Leicester, United Kingdom

²International Diabetes Center, Park Nicollet Health Services, Minneapolis, Minnesota

³Atlanta Diabetes Associates, Atlanta, Georgia

⁴Northwestern University, Chicago, Illinois

⁵National Research Institute, Los Angeles, California

⁶Novo Nordisk A/S, Søborg, Denmark

⁷Texas Diabetes Institute, San Antonio

Publication details:

Davies MJ, Bergenstal R, Bode B, Kushner RF, Lewin A, Skjøth TV, Andreasen AH, Jensen CB, and DeFronzo RA (2015). **Efficacy of Liraglutide for Weight Loss Among Patients With Type 2 Diabetes: The SCALE Diabetes Randomized Clinical Trial.** *JAMA*. 314 (7), 687-699. DOI: 10.1001/jama.2015.9676. PMID: 26284720.

Link to the journal page for you to Tweet about this article or post it on

Facebook: <http://bit.ly/1hIMkN7>

Please note: because of copyright restrictions, the full article can only be shared outside our organisation if it complies with the publishers' criteria.

I can send you a pdf of the published article on request for internal use only.

ABSTRACT

Importance

Weight loss of 5% to 10% can improve type 2 diabetes and related comorbidities. Few safe, effective weight-management drugs are currently available.

Objective

To investigate efficacy and safety of liraglutide vs placebo for weight management in adults with overweight or obesity and type 2 diabetes.

Design, Setting and Participants

Fifty-six-week randomized (2:1:1), double-blind, placebo-controlled, parallel-group trial with 12-week observational off-drug follow-up period. The study was conducted at 126 sites in 9 countries between June 2011 and January 2013. Of 1361 participants assessed for eligibility, 846 were randomized. Inclusion criteria were body mass index of 27.0 or greater, age 18 years or older, taking 0 to 3 oral hypoglycemic agents (metformin, thiazolidinedione, sulfonylurea) with stable body weight, and glycated hemoglobin level 7.0% to 10.0%.

Interventions

Once-daily, subcutaneous liraglutide (3.0 mg) (n = 423), liraglutide (1.8 mg) (n = 211), or placebo (n = 212), all as adjunct to 500 kcal/d dietary deficit and increased physical activity (≥ 150 min/wk).

Main Outcomes and Measures

Three coprimary end points: relative change in weight, proportion of participants losing 5% or more, or more than 10%, of baseline weight at week 56.

Results

Baseline weight was 105.7 kg with liraglutide (3.0-mg dose), 105.8 kg with liraglutide (1.8-mg dose), and 106.5 kg with placebo. Weight loss was 6.0% (6.4 kg) with liraglutide (3.0-mg dose), 4.7% (5.0 kg) with liraglutide (1.8-mg dose), and 2.0% (2.2 kg) with placebo (estimated difference for liraglutide [3.0 mg] vs placebo, -4.00% [95% CI, -5.10% to -2.90%]; liraglutide [1.8 mg] vs placebo, -2.71% [95% CI, -4.00% to -1.42%]; $P < .001$ for both). Weight loss of 5% or greater occurred in 54.3% with liraglutide (3.0 mg) and 40.4% with liraglutide (1.8 mg) vs 21.4% with placebo (estimated difference for liraglutide [3.0 mg] vs placebo, 32.9% [95% CI, 24.6% to 41.2%]; for liraglutide [1.8 mg] vs placebo, 19.0% [95% CI, 9.1% to 28.8%]; $P < .001$ for both). Weight loss greater than 10% occurred in 25.2% with liraglutide (3.0 mg) and 15.9% with liraglutide (1.8 mg) vs 6.7% with placebo (estimated difference for liraglutide [3.0 mg] vs placebo, 18.5% [95% CI, 12.7% to 24.4%], $P < .001$; for liraglutide [1.8 mg] vs placebo, 9.3% [95% CI, 2.7% to 15.8%], $P = .006$). More gastrointestinal disorders were reported with liraglutide (3.0 mg) vs liraglutide (1.8 mg) and placebo. No pancreatitis was reported.

Conclusions and Relevance

Among overweight and obese participants with type 2 diabetes, use of subcutaneous liraglutide (3.0 mg) daily, compared with placebo, resulted in weight loss over 56 weeks. Further studies are needed to evaluate longer-term efficacy and safety.

Trial Registration: clinicaltrials.gov Identifier: [NCT01272232](https://clinicaltrials.gov/ct2/show/study/NCT01272232)