

HEAD-TO-HEAD STUDY: OZEMPIC® VS TRULICITY®

SUSTAIN 7

AUTHORS

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Ozempic® versus Trulicity® once weekly in patients with type 2 diabetes: a randomized, open-label, phase 3b trial



OBJECTIVE: To compare the efficacy and safety of Ozempic® (semaglutide) vs Trulicity® (dulaglutide) on glycemic control at low doses and high doses in patients with type 2 diabetes inadequately controlled on metformin monotherapy.

Indications and Limitations of Use

Ozempic® (semaglutide) injection 0.5 mg or 1 mg is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular (CV) events (CV death, nonfatal myocardial infarction, or nonfatal stroke) in adults with type 2 diabetes mellitus and established CV disease.

- Ozempic® has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Ozempic® is not indicated for use in patients with type 1 diabetes mellitus.

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

- In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Ozempic® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.
- Ozempic® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Ozempic® and inform them of symptoms of thyroid tumors (eg, a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Ozempic®.

Contraindications

- Ozempic® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with a prior hypersensitivity reaction to semaglutide or to any of the excipients in Ozempic®. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with Ozempic®.

Warnings and Precautions

- **Risk of Thyroid C-Cell Tumors:** Patients should be referred to an endocrinologist for further evaluation if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging.
- **Pancreatitis:** Acute and chronic pancreatitis have been reported in clinical studies. Observe patients carefully for signs and symptoms of pancreatitis (persistent severe abdominal pain, sometimes radiating to the back with or without vomiting). If pancreatitis is suspected, discontinue Ozempic® promptly, and if pancreatitis is confirmed, do not restart.



Please see Important Safety Information throughout. Please see Prescribing Information, including Boxed Warning, at <http://www.novo-pi.com/ozempic.pdf>.

ONCE-WEEKLY
OZEMPIC®
semaglutide injection 0.5mg/1mg

STUDY DESIGN AND RESULTS¹



STUDY DESIGN AND METHODOLOGY

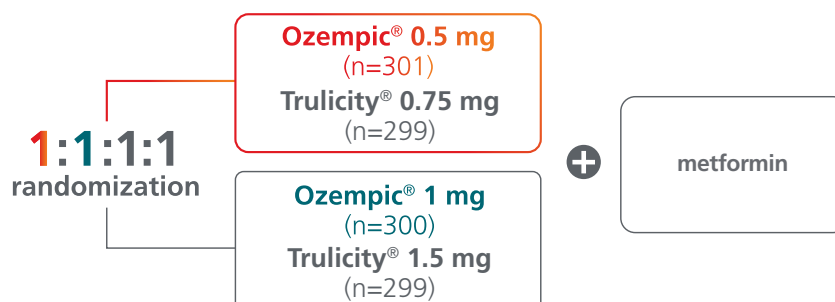
A 40-week, multinational, multicenter, randomized, open-label, 4-armed, pairwise, active-controlled, parallel-group trial to compare the efficacy and safety of Ozempic® vs Trulicity® in 1201 adult patients with type 2 diabetes.

BACKGROUND



Despite common mechanisms of action, glucagon-like peptide-1 receptor agonists differ in structure, pharmacokinetic profile, and clinical effects. This head-to-head trial compared semaglutide with dulaglutide in patients with inadequately controlled type 2 diabetes.

STUDY DURATION AND GROUPS



INCLUSION CRITERIA

- A1C: 7% to 10.5%
- Stable treatment with metformin (≥1500 mg/day or maximum tolerated dose) for at least 90 days prior to screening

Primary endpoint:

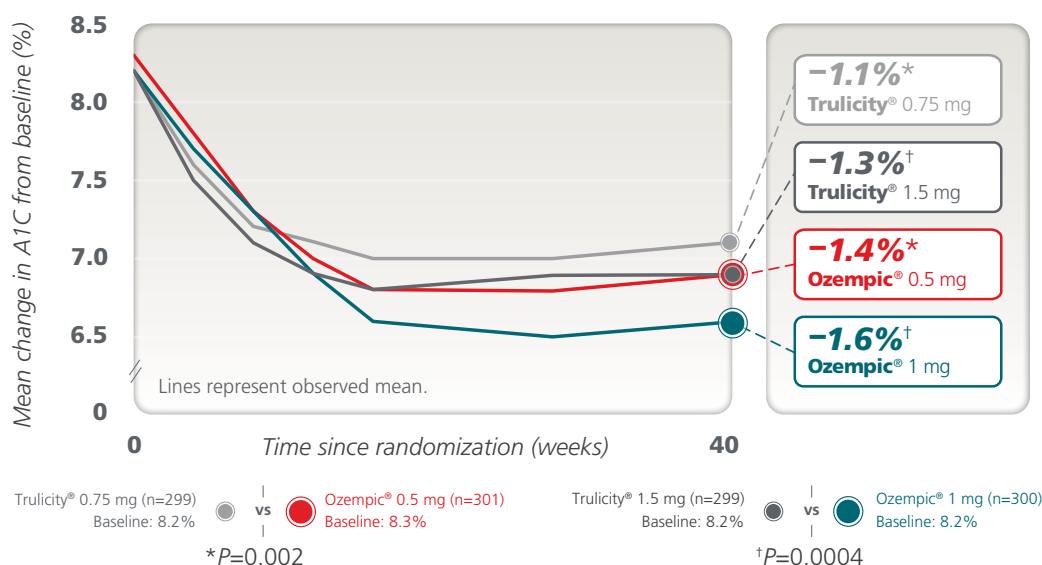
Change in A1C from baseline at Week 40.

Secondary endpoints:

- ▶ Change in mean body weight from baseline at Week 40
- ▶ Proportion of patients achieving A1C <7% at Week 40

PRIMARY ENDPOINT: MEAN CHANGE IN A1C FROM BASELINE TO WEEK 40^{1,2}

Ozempic® demonstrated superior A1C reductions vs Trulicity® for each dose comparison.



Results based on a sensitivity analysis of retrieved dropout population. SUSTAIN 7 was only powered to detect differences in A1C from baseline to Week 40.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Diabetic Retinopathy Complications:** In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with Ozempic® (3.0%) compared with placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline than among patients without a known history of diabetic retinopathy. Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.
- **Never Share an Ozempic® Pen Between Patients:** Ozempic® pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens.



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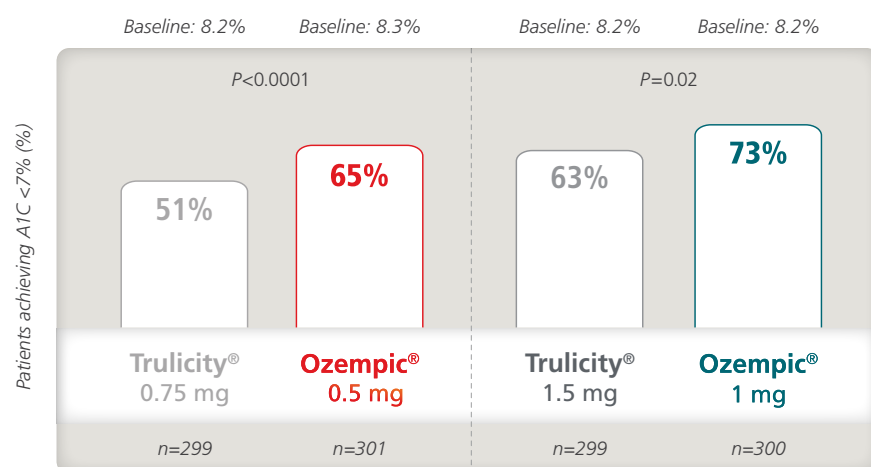
ONCE-WEEKLY
OZEMPIC®
semaglutide injection 0.5mg|1mg

SUMMARY OF RESULTS¹



At low and high doses, semaglutide was superior to dulaglutide in improving glycemic control, enabling a significantly greater number of patients with type 2 diabetes to achieve clinically meaningful glycemic targets, with a similar safety profile.

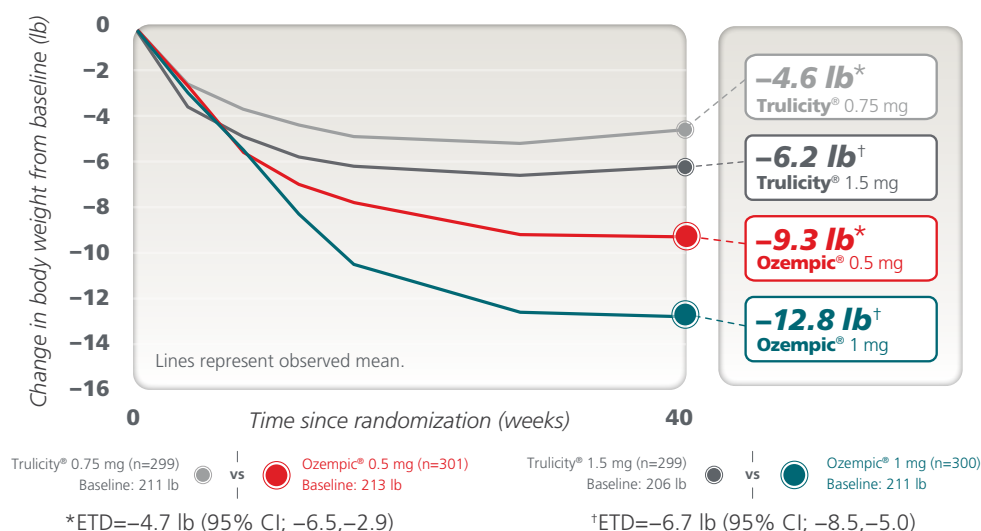
SECONDARY ENDPOINT: PROPORTION OF PATIENTS WHO ACHIEVED A1C <7% AT WEEK 40



A greater percentage of patients achieved A1C <7% with Ozempic® vs Trulicity® for each dose comparison.

Predefined secondary endpoint analyzed using post hoc analysis of retrieved dropout population.

SECONDARY ENDPOINT: MEAN CHANGE IN BODY WEIGHT FROM BASELINE TO WEEK 40^{1,2}



Ozempic® demonstrated superior body weight reductions vs Trulicity® for each dose comparison.

Ozempic® is not indicated for weight loss.

Results based on a sensitivity analysis of retrieved dropout population.
ETD was from baseline to Week 40.
ETD=estimated treatment difference; CI=confidence interval.

Please see Prescribing Information, including Boxed Warning, at <http://www.novo-pi.com/ozempic.pdf>.

Important Safety Information (cont'd)

- Hypoglycemia:** Patients receiving Ozempic® in combination with an insulin secretagogue (eg, sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.
- Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Ozempic® in patients reporting severe adverse gastrointestinal reactions.



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ONCE-WEEKLY
OZEMPIC®
semaglutide injection 0.5mg | 1mg

SAFETY¹

ADVERSE EVENTS OCCURRING IN ≥5% OF PATIENTS

SUSTAIN 7 was not designed to evaluate relative safety between Ozempic® and Trulicity®.

	Trulicity® 0.75 mg (n=299) %	Ozempic® 0.5 mg (n=301) %	Trulicity® 1.5 mg (n=299) %	Ozempic® 1 mg (n=300) %
Nausea	13	23	20	21
Diarrhea	8	14	18	14
Vomiting	4	10	10	10
Decreased appetite	3	8	10	9
Headache	4	8	6	7
Lipase increased	5	7	6	6
Nasopharyngitis	6	5	7	5
Upper respiratory tract infection	7	5	5	3
Constipation	3	5	5	5
GI AEs leading to treatment discontinuation	2	5	5	6

- In placebo-controlled trials, the most common adverse reactions reported in ≥5% of patients treated with Ozempic® were nausea, vomiting, diarrhea, abdominal pain, and constipation³
- Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice³
- Comparator AE rates are not an adequate basis for comparison of safety between products

GI=gastrointestinal; AE=adverse event.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Hypersensitivity:** Serious hypersensitivity reactions (eg, anaphylaxis, angioedema) have been reported in patients treated with Ozempic®. If hypersensitivity reactions occur, discontinue use of Ozempic®; treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist.

Adverse Reactions

- The most common adverse reactions, reported in ≥5% of patients treated with Ozempic® are nausea, vomiting, diarrhea, abdominal pain, and constipation.

Drug Interactions

- When initiating Ozempic®, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia.
- Ozempic® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications, so caution should be exercised.

Use in Specific Populations

- There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Discontinue Ozempic® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide.

References: 1. Pratley RE, Aroda VR, Lingvay I, et al. Semaglutide versus dulaglutide once weekly in patients with type 2 diabetes: a randomised, open-label, phase 3b trial. *Lancet Diabetes Endocrinol.* 2018;6(4):275-286. 2. Data on file. Novo Nordisk Inc; Plainsboro, NJ. 3. Ozempic® [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2021.



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