



Efficacy and safety of oral semaglutide versus placebo in children and adolescents with type 2 diabetes

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Main Information

Primary registry identifying number

LBCTR2021014721

Protocol number

NN9924-4437

MOH registration number

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Prospective

Type of registration: Justify

N/A

Date of registration in national regulatory agency

12/01/2021

Primary sponsor

Novo Nordisk A/S

Primary sponsor: Country of origin

Denmark

Date of registration in primary registry

03/04/2021

Date of registration in national regulatory agency

12/01/2021

Public title

Efficacy and safety of oral semaglutide versus placebo in children and adolescents with type 2 diabetes

Acronym

PIONEER TEENS

Scientific title

Efficacy and safety of oral semaglutide versus placebo both in combination with metformin and/or basal insulin in children and adolescents with type 2 diabetes

Acronym

PIONEER TEENS

Brief summary of the study: English

PIONEER TEENS (NN9924-4437) will be conducted to confirm the efficacy and safety of oral semaglutide in the paediatric population to address the unmet need for treatment of children and adolescents 10 to <18 years of age with type 2 diabetes. Further, the trial will explore the beta-cell function-preserving effects of oral semaglutide during treatment and after a period of 12 weeks off-trial product following the 52-week treatment period.

Brief summary of the study: Arabic

تهدف هذه الدراسة لمقارنة دوائين لعلاج داء السكري من النوع الثاني سيماغلو تيد دواء جديد ودواء وهمي. سيقوم الباحثون باختبار سيماغلو تيد لمعرفة مدى فعاليته مقارنة بالدواء الوهمي. سبق أن اختبر الباحثون سيماغلو تيد على البالغين. ستختبر الدراسة أيضاً ما إذا كان سيماغلو تيد آمناً للأطفال والمراهقين.

Health conditions/problem studied: Specify

Type two diabetes in paediatric population

Interventions: Specify

Subjects will, after a 2-week screening period, be randomised in a 1:1 manner to receive either oral semaglutide or placebo.

Key inclusion and exclusion criteria: Inclusion criteria





Inclusion criteria:

Subjects are eligible to be included in the trial only if all of the following criteria apply:

1. Informed consent from parent(s) or legally acceptable representative (LAR) and child assent from the subject obtained before any trial-related activities. Trial-related activities are any procedures that are carried out as part of the trial, including activities to determine suitability for the trial.
2. Male or female, aged 10 to <18 years at the day of randomisation
3. Diagnosed with type 2 diabetes mellitus according to the ADA criteria and treated with:
 - stable metformin dose* or
 - stable metformin dose* and a stable dose of basal insulin** or
 - stable dose of basal insulin**

*stable metformin dose is defined as at least 1000 mg daily or the maximum tolerated dose for 56 days or longer prior to screening.

**stable dose of basal insulin is defined as basal insulin treatment ≥ 30 days prior to screening, compared to the dose at screening, dose adjustments of $\pm 25\%$ are allowed.
4. HbA1c 6.5%–11.0% (47–97 mmol/mol) (both inclusive)
5. Ability and willingness to adhere to the protocol including self-measurement of plasma glucose according to the protocol.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

10

Key inclusion and exclusion criteria: Age maximum

17

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion criteria:

Subjects are excluded from the trial if any of the following criteria apply:

1. Known or suspected hypersensitivity to trial product(s) or related products.
2. Previous participation in this trial. Participation is defined as randomisation. Re-screening is allowed, however there must be at least 90 days between screenings.
3. Female who is pregnant, breast-feeding or intends to become pregnant or is of childbearing potential and not using highly effective contraceptive methods, refer to Appendix 5.
4. Receipt of any investigational medicinal product within 30 days before screening.
5. Any disorder, which, in the opinion of the investigator, might jeopardise subject's safety or compliance with the protocol.
6. Any laboratory safety parameter at screening outside the below extended laboratory ranges:
 - ALT ≥ 2.5 times the upper normal limit (UNL)
 - creatinine >UNL for age in children unless renal function is proven normal by further assessments at the discretion of the investigator
 - C-peptide <1.5 ng/mL
 - calcitonin ≥ 50 ng/L
7. Personal or first degree relative(s) history of multiple endocrine neoplasia type 2 or medullary thyroid carcinoma.
8. History or presence of pancreatitis (acute or chronic).
9. Known history of heart disease (including history of clinically significant arrhythmias or conduction delays on ECG) within 180 days of visit 1, new clinically significant arrhythmias or conduction delays on ECG identified at visit 1.
10. Known hypoglycaemic unawareness as indicated by the investigator according to Clarke's questionnaire question 82.
11. Recurrent severe hypoglycaemic episodes within the last year as judged by the investigator.
12. Uncontrolled hypertension, treated or untreated, >99th percentile for age and gender in children and adolescents. If "white coat hypertension" is suspected at visit 1 a repeat blood pressure measurement either during visit 1 or at visit 2 prior to other trial related activities is allowed, with the last measurement being conclusive.
13. Treatment with any medication for the indication of diabetes other than stated in the inclusion criteria in a period of 90 days before screening. However, short-term treatment with bolus insulin for a metabolic decompensation/intercurrent illness for a maximum of 14 days prior to the day of visit 1 is allowed.
14. Uncontrolled and potentially unstable diabetic retinopathy or maculopathy documented by an ophthalmologic examination of the retina preferably supported by a fundus photography or optical coherence tomography within the past 90 days prior to screening or in the period between screening and randomisation (visit 2). Pharmacological pupil-dilation is a requirement unless using a digital fundus photography camera specified for non-dilated examination.
15. Presence or history of malignant neoplasm within 5 years prior to the day of screening. Basal and squamous cell skin cancer and any carcinoma in-situ is allowed.
16. Diagnosis of type 1 diabetes
17. Positive insulinoma associated-protein 2 (IA-2) antibodies or anti-glutamic acid decarboxylase (anti-GAD) antibodies.
18. Maturity onset diabetes of the young (MODY).
19. History of major surgical procedures involving the stomach potentially affecting absorption of trial product (e.g. subtotal and total gastrectomy, sleeve gastrectomy or gastric bypass surgery).

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope	Trial scope: Specify scope	
Safety	N/A	
Study design: Allocation	Study design: Masking	
Randomized controlled trial	Blinded (masking used)	
Study design: Control	Study phase	
Placebo	3	
Study design: Purpose	Study design: Specify purpose	
Treatment	N/A	
Study design: Assignment	Study design: Specify assignment	
Parallel	N/A	
IMP has market authorization	IMP has market authorization: Specify	
Yes, Worldwide	27 EU countries and UK	
Name of IMP	Year of authorization	Month of authorization
Oral Semaglutide	2020	4
Type of IMP		
Others		
Pharmaceutical class		
Anti-Diabetic		
Therapeutic indication		
Type Two Diabetes in paediatric patients		
Therapeutic benefit		
PIONEER TEENS (NN9924-4437) will be conducted to confirm the efficacy and safety of oral semaglutide in the paediatric population to address the unmet need for treatment of children and adolescents 10 to <18 years of age with type 2 diabetes		
Study model	Study model: Explain model	
N/A	N/A	
Study model: Specify model		
N/A		
Time perspective	Time perspective: Explain time perspective	
N/A	N/A	
Time perspective: Specify perspective		
N/A		
Target follow-up duration	Target follow-up duration: Unit	
Number of groups/cohorts		
Biospecimen retention	Biospecimen description	



Samples without DNA

- HbA1c
- Fasting glucagon
- Fasting insulin
- Fasting pro-insulin
- Fasting plasma glucose (FPG)¹
- Fasting pro-insulin to insulin ratio
- Fasting C-peptide
- Random C-peptide (i.e. not fasting at visit 1)
- Homeostasis model assessment (HOMA-B and HOMA-IR)
- Plasma glucose, fasting and non-fasting
- C-peptide, fasting and non-fasting
- Insulin, fasting and non-fasting
- Glucagon, fasting and non-fasting
- Cholesterol
- High density lipoprotein (HDL) cholesterol
- Low density lipoprotein (LDL) cholesterol
- Triglycerides
- Very low density lipoprotein (VLDL) cholesterol
- Erythrocytes
- Haematocrit
- Haemoglobin
- Leucocytes
- Thrombocytes
- Differential count: eosinophils, basophils, lymphocytes, monocytes, neutrophils
- Alanine Aminotransferase (ALT)²
- Albumin
- Alkaline phosphatase (ALP)
- Amylase
- Aspartate Aminotransferase (AST)
- Bilirubin (total)
- Calcium
- Creatine kinase
- Creatinine²
- Lipase
- Potassium
- Sodium
- Urea and calcium (albumin corrected urea)
- Lactate
- Insulin-like growth factor 1 (IGF-1)
- Insulin-like growth factor binding protein 3 (IGFBP-3)
- Anti-glutamic acid decarboxylase (anti-GAD) antibodies
- Insulinoma associated-protein 2 (IA-2) antibodies
- Calcitonin
- Dehydroepiandrosterone sulphate (DHEAS)
- Estradiol (for girls)
- Follicle stimulating hormone (FSH)
- Luteinizing hormone (LH)
- Prolactin
- Testosterone (for boys)
- Thyroid stimulating hormone (TSH)

Target sample size

132

Date of first enrollment: Type

Anticipated

Date of study closure: Type

Anticipated

Recruitment status

Not recruiting

Date of completion

IPD sharing statement plan

Actual enrollment target size

Date of first enrollment: Date

31/03/2021

Date of study closure: Date

26/03/2025

Recruitment status: Specify

IPD sharing statement description



No

It will not be shared

Additional data URL

U1111-1218-1527

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
NA	NA

Sources of Monetary or Material Support

Name
Novo Nordisk A/S

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Badiaa Masri	Sin El fil	Lebanon	009611488664	bams@novonordisk.com	Novo Nordisk
Scientific	Rita Habib	Sin El Fil	Lebanon	009611488664	rteb@novonordisk.com	Novo Nordisk
Scientific	Charles Saab	Baabda	Lebanon	009613253944	drsaab@hotmail.com	Chronic Care Center



Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Chronic Care Center	Dr. Charles Saab	Endocrinologist	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Chronic Care Center	11/12/2020	Michelle Abi Saad	cccmass@chroniccare.org.lb	009615455101

Countries of Recruitment

Name
Mexico
Russian Federation
United States of America
Netherlands
Portugal
Greece
Czech Republic
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
type 2 diabetes	Obesity (E66)	T2D



Interventions

Intervention	Description	Keyword
To confirm superiority of oral semaglutide at the maximum tolerated dose* (3 mg, 7 mg or 14 mg)	confirm the efficacy and safety of oral semaglutide in the paediatric population to address the unmet need for treatment of children and adolescents 10 to <18 years of age with type 2 diabetes. Further, the trial will explore the beta-cell function-preserving effects of oral semaglutide during treatment and after a period of 12 weeks offtrialproduct following the 52-week treatment period.	T2D

Primary Outcomes

Name	Time Points	Measure
Change from baseline (week 0) to week 26 in glycosylated haemoglobin (HbA1c) (%-point and	week 0 to week 26	HbA1c

Key Secondary Outcomes

Name	Time Points	Measure
Fasting plasma glucose (FPG) (mmol/L)	week 0 to week 26	FPG
Body mass index (BMI) standard deviation score (SDS)	week 0 to week 26	BMI



Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files