A randomised controlled clinical trial in type 2 diabetes comparing semaglutide to placebo and liraglutide

This trial was conducted in Europe, Asia, and Africa. Study participants were randomised evenly to treatment with semaglutide (0.1 mg QW - 1.6 mg QW, 6 treatment arms, placebo or liraglutide (1.2 mg QD, or 1.8 mg QD). Treatment allocation to semaglutide or placebo was double-blind, whereas liraglutide treatment was administered open-label. Primary efficacy parameter was HbA1c and the treatment duration was 12 weeks.

Scientific Title
Investigation of safety and efficacy of five doses of semaglutide versus placebo and open-label liraglutide, as add on therapy, in subjects diagnosed with type 2 diabetes currently treated with metformin or controlled with diet and exercise A 12 week multi-centre, multi national, double-blind, placebo-controlled, randomised, nine armed parallel group, dose finding trial

**Trial IDs and acronym(s)**

- **Novo Nordisk Trial ID**
  - NN9535-1821
- **Clinical Trials.gov Registration**
  - NCT00696657
- **Other Identifier(s)**
  - EudraCT Number: 2007-003956-12

**Condition**
- Diabetes
- Diabetes Mellitus, Type 2

**Trial dates**
- Start date: 03. Jun. 2008
- Primary completion date: 05. Feb. 2009
- Completion date: 05. Feb. 2009

**Trial phase**
- Phase 2

**Treatment**
- semaglutide
- placebo
- liraglutide

**Arm Information with Assigned Treatment**
- No. of arms: 14
- **A (Experimental):**
  - Arm description:
  - Drug: semaglutide
  - 0.1 mg, once weekly, s.c. injection
B (Experimental):
Arm description:
Drug: semaglutide
0.2 mg, once weekly, s.c. injection

C (Experimental):
Arm description:
Drug: semaglutide
0.4 mg, once weekly, s.c. injection

D (Experimental):
Arm description:
Drug: semaglutide
0.8 mg, once weekly, s.c. injection

E (Experimental):
Arm description:
Drug: semaglutide
0.8 mg with titration, once weekly, s.c. injection

F (Experimental):
Arm description:
Drug: semaglutide
1.6 mg with titration, once weekly, s.c. injection

G1 (Placebo Comparator):
Arm description:
Drug: placebo
0.1 mg, once weekly, s.c. injection

G2 (Placebo Comparator):
Arm description:
Drug: placebo
0.2 mg, once weekly, s.c. injection

G3 (Placebo Comparator):
Arm description:
Drug: placebo
0.4 mg, once weekly, s.c. injection

G4 (Placebo Comparator):
Arm description:
Drug: placebo
0.8 mg with titration, once weekly, s.c. injection

G5 (Placebo Comparator):
Arm description:
Drug: placebo
0.8 mg with titration, once weekly, s.c. injection

- G6 (Placebo Comparator):
  Arm description:
  Drug: placebo
  1.6 mg, once weekly, s.c. injection

- H (Experimental):
  Arm description:
  Drug: liraglutide
  1.2 mg with titration, once daily, s.c. injection

- I (Experimental):
  Arm description:
  Drug: liraglutide
  1.8 mg with titration, once daily, s.c. injection

<table>
<thead>
<tr>
<th>Trial status</th>
<th>No. of trial participants</th>
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<tr>
<td>Completed</td>
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<table>
<thead>
<tr>
<th>Age eligible for trial participation</th>
<th>Genders eligible for trial participation</th>
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<tr>
<td>18 years and above</td>
<td>Both</td>
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<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tr>
<td>- Men and women-not-of-childbearing</td>
<td>- Treatment with insulin, GLP-1 receptor agonists (including liraglutide), dipeptidyl peptidase-4 inhibitors, sulphonylurea, thiazolidinediones, Alpha-GIs, or any investigational drug, within the last three months</td>
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<td>potential diagnosed with type 2 diabetes for</td>
<td>- Impaired liver or kidney function</td>
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<td>at least three months</td>
<td>- Proliferative retinopathy or maculopathy requiring acute treatment</td>
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<td>- Stable treatment regimen with either metformin (at</td>
<td>- Clinically significant active cardiovascular disease and uncontrolled treated/untreated hypertension</td>
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<td>1500 mg) or diet and exercise alone for at least</td>
<td>- Recurrent major hypoglycaemia or hypoglycaemic unawareness</td>
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<td>three months</td>
<td>- Present or planned use of any drug which could interfere with the glucose levels (e.g. systemic corticosteroids)</td>
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<td>- HbA1c: 7.0-10.0 % (both inclusive)</td>
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<td>- Body weight between 60 kg and 110 kg</td>
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<tr>
<th>Trial type</th>
<th>Trial design</th>
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http://www.novonordisk-trials.com
<table>
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<tr>
<th>Interventional</th>
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<tbody>
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<td>Allocation: Randomized</td>
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<td>Control: Placebo Control</td>
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<td>Assignment: Parallel Assignment</td>
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**Primary outcome**
- HbA1c
  Time frame: after 12 weeks of treatment

**Secondary outcome(s)**
- Percentage of subjects with an adverse events
  Time frame: after 12 weeks of treatment
- Percentage of subjects with hypoglycaemic episode
  Time frame: after 12 weeks of treatment
- Change from baseline in ECG
  Time frame: week 0, week 12
- Change from baseline in vital signs (Pulse)
  Time frame: week 0, week 12
- Change from baseline in vital signs (blood pressure)
  Time frame: week 0, week 12
- Change from baseline in standard safety laboratory parameters (haematology)
  Time frame: week 0, week 12
- Change from baseline in standard safety laboratory parameters (biochemistry)
  Time frame: week 0, week 12
- Change from baseline in standard safety laboratory parameters (urinalysis)
  Time frame: week 0, week 12
- Change from baseline in calcitonin
  Time frame: week 0, week 12
- Percentage of subjects developing anti-semaglutide antibodies
  Time frame: after 12 weeks of treatment

**Participating countries**
- Austria: Completed/Suspended
- Bulgaria: Completed
- Finland: Completed/Suspended
- Former Serbia and Montenegro: Completed
- France: Completed/Suspended
- Germany: Completed
- Hungary: Completed/Suspended
- India: Completed/Suspended
- Italy: Completed/Suspended
- South Africa: Completed/Suspended

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Spain: Completed/Suspended
Switzerland: Completed/Suspended
Turkey: Completed/Suspended
United Kingdom: Completed/Suspended

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<th>Central contact information</th>
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<tbody>
<tr>
<td>Trial sponsored by: Novo Nordisk A/S</td>
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<tr>
<td>Contact: <a href="mailto:clinicaltrials@novonordisk.com">clinicaltrials@novonordisk.com</a></td>
</tr>
<tr>
<td>For trials conducted in the US: (+1) 866-867-7178</td>
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Information provided by Novo Nordisk A/S
PDF generation date: 10.Oct.2017

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