The efficacy and safety of liraglutide as adjunct therapy to insulin in the treatment of type 1 diabetes

This trial is conducted globally. The aim of the trial is to confirm the efficacy and safety of liraglutide as adjunct therapy to insulin in the treatment of type 1 diabetes. The total trial duration per subject is approximately 58 weeks.

**Scientific Title**
The efficacy and safety of liraglutide as adjunct therapy to insulin in the treatment of type 1 diabetes. A 52-week randomised, treat-to-target, placebo-controlled, double blinded, parallel group, multinational, multi-centre trial

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**Trial IDs and acronym(s)**
**Novo Nordisk Trial ID**
NN9211-3919

**Clinical Trials.gov Registration**
NCT01836523

**Other Identifier(s)**
EudraCT Number: 2012-003580-21
Other Identifier: U11111-1133-0590

**Condition**
Diabetes
Diabetes Mellitus, Type 1

**Trial dates**
Start date: 30.Nov.2013
Primary completion date: 30.Jun.2015
Completion date: 30.Jun.2015

**Trial phase**
Phase 3

**Treatment**
- liraglutide
- placebo

**Arm Information with Assigned Treatment**
No. of arms: 6
- Liraglutide 0.6 mg + insulin (Experimental):
  Arm description:
  Drug: liraglutide
  Subjects randomised to 0.6 mg liraglutide treatment or liraglutide placebo as an add-on to their pre-trial insulin treatment will remain on this dose throughout the study (52 weeks). Administered subcutaneously (s.c., under the skin) once daily.
- Liraglutide 1.2 mg + insulin (Experimental):

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Arm description:
Drug: liraglutide
Subjects randomised to 0.6 mg liraglutide treatment or liraglutide placebo as an add-on to their pre-trial insulin treatment will remain on this dose throughout the study (52 weeks). Administered subcutaneously (s.c., under the skin) once daily.

- **Liraglutide 1.8 mg + insulin (Experimental):**
  Arm description:
  Drug: liraglutide
  Subjects randomised to 0.6 mg liraglutide treatment or liraglutide placebo as an add-on to their pre-trial insulin treatment will remain on this dose throughout the study (52 weeks). Administered subcutaneously (s.c., under the skin) once daily.

- **Liraglutide placebo 0.6 mg + insulin (Placebo Comparator):**
  Arm description:
  Drug: placebo
  Subjects randomised to 0.6 mg liraglutide treatment or liraglutide placebo as an add-on to their pre-trial insulin treatment will remain on this dose throughout the study (52 weeks). Administered subcutaneously (s.c., under the skin) once daily.

- **Liraglutide placebo 1.2 mg + insulin (Placebo Comparator):**
  Arm description:
  Drug: placebo
  Subjects randomised to 0.6 mg liraglutide treatment or liraglutide placebo as an add-on to their pre-trial insulin treatment will remain on this dose throughout the study (52 weeks). Administered subcutaneously (s.c., under the skin) once daily.

- **Liraglutide placebo 1.8 mg + insulin (Placebo Comparator):**
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<table>
<thead>
<tr>
<th><strong>Trial status</strong></th>
<th><strong>No. of trial participants</strong></th>
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<tbody>
<tr>
<td>Completed</td>
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<table>
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<tr>
<th><strong>Age eligible for trial participation</strong></th>
<th><strong>Genders eligible for trial participation</strong></th>
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<tr>
<td>18 years to 75 years</td>
<td>Both</td>
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<tr>
<th><strong>Inclusion criteria</strong></th>
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<tr>
<td>- Informed consent obtained</td>
<td>- Prior use of glucagon-like peptide-1 (GLP-1) receptor agonist or dipeptidyl peptidase IV (DPP-4) inhibitors</td>
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<td>- Type 1 diabetes mellitus for 12 months or longer</td>
<td>- Use of any medication, which in the</td>
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<td>- Basal bolus or CSII (Continuous)</td>
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Subcutaneous Insulin Infusion, insulin pump) treatment for 6 months or longer
- Stable insulin treatment for the last 3 months prior to Screening, as judged and documented by the investigator
- HbA1c 7.0-10% (Diabetes Control and Complications Trial (DCCT)), both inclusive, (corresponding to 53-86 mmol/mol (International Federation of Clinical Chemistry (IFCC))
- Ability and willingness to comply with all protocol procedures e.g. correct handling of trial product, complete trial related questionnaires, diaries, self-monitoring of plasma glucose, self titration of insulin and attend all scheduled visits

investigator’s opinion could interfere with the glycaemic control or affect the subject’s safety. Premix insulin is not allowed
- Known proliferative retinopathy or maculopathy requiring acute treatment
- Severe neuropathy, in particular autonomic neuropathy, i.e. gastroparesis, as judged by the investigator
- Uncontrolled/ untreated blood pressure at screening above 160 mmHg for systolic or above 100 mmHg for diastolic
- History of acute or chronic pancreatitis
- Screening calcitonin value equal to or above 50 ng/L
- Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia type 2 (MEN2)
- Diagnosis of malignant neoplasm in the previous 5 years (except basal cell skin cancer or squamous cell skin cancer)

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<th>Intervventional</th>
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| Trial design | Purpose: Treatment  
Allocation: Randomized  
Masking: Double Blind  
Control: Placebo Control  
Assignment: Parallel Assignment |

| Primary outcome | Change from baseline in HbA1c (glycosylated haemoglobin)  
Time frame: Week 0, week 52  
Change from baseline in body weight  
Time frame: Week 0, week 52  
Change from baseline in total daily insulin dose  
Time frame: Week 0, week 52 |
|----------------|-----------------------------------------------------------|

| Secondary outcome(s) | Number of treatment-emergent symptomatic hypoglycaemic episodes  
Time frame: Weeks 0-52 |

| Participating countries | Argentina: Completed  
Australia: Completed  
Belgium: Completed  
Canada: Completed/Suspended  
Finland: Completed/Suspended  
France: Completed  
Germany: Completed/Suspended |

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**Central contact information**

Trial sponsored by: Novo Nordisk A/S  
Contact: clinicaltrials@novonordisk.com  
For trials conducted in the US: (+1) 866-867-7178

**Labeling information**

- **EU:**  


Information provided by Novo Nordisk A/S  
PDF generation date: 04.Jan.2018