Effect of Liraglutide on Body Weight in Non-diabetic Obese Subjects or Overweight Subjects With Co-morbidities: SCALE™ - Obesity and Pre-diabetes

This trial is conducted in Africa, Asia, Europe, Oceania, North America and South America.

The aim of this clinical trial is to evaluate the potential of liraglutide to induce and maintain weight loss over 56 weeks in obese subjects or overweight subjects with co-morbidities. Furthermore, the aim is to investigate the long term potential of liraglutide to delay the onset of type 2 diabetes in subjects diagnosed with pre-diabetes at baseline.

Based on body mass index (BMI) and pre-diabetes status, subjects will be randomised to either 68 weeks (56 weeks of randomised treatment followed by a 12 week re-randomised treatment period) or 160 weeks of treatment (160 week treatment will only be applicable to subjects with pre-diabetes status at baseline).

Scientific Title
Effect of Liraglutide on Body Weight in Non-diabetic Obese Subjects or Overweight Subjects With Co-morbidities: A Randomised, Double-blind, Placebo Controlled, Parallel Group, Multi-centre, Multinational Trial With Stratification of Subject to either 56 or 160 Weeks of Treatment Based on Pre-diabetes Status at Randomisation

<table>
<thead>
<tr>
<th>Trial IDs and acronym(s)</th>
<th>Condition</th>
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<tbody>
<tr>
<td>Novo Nordisk Trial ID</td>
<td>Obesity</td>
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<tr>
<td>NN8022-1839</td>
<td>Metabolism and nutrition disorder</td>
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<td>Clinical Trials.gov Registration</td>
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<td>NCT01272219</td>
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<td>Other Identifier(s)</td>
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<td>Other Identifier: U1111-1118-7871</td>
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<th>Trial dates</th>
<th>Trial phase</th>
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<tr>
<td>Start date: 01.Jun.2011</td>
<td>Phase 3</td>
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<td>Primary completion date: 18.Mar.2013</td>
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<td>Completion date: 02.Mar.2015</td>
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<tr>
<th>Treatment</th>
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<tbody>
<tr>
<td>• liraglutide</td>
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<tr>
<td>• placebo</td>
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http://www.novonordisk-trials.com
Arm Information with Assigned Treatment

No. of arms: 5

- **Liraglutide 3.0mg (week0-56)/Liraglutide 3.0mg (week56-68) (Experimental):**
  Arm description:
  Drug: liraglutide
  Subject with no pre-diabetes at screening, receiving liraglutide 3.0 mg subcutaneous (under the skin) injection once daily for 56 weeks. Subjects completing 56 weeks are re-randomised to receive liraglutide 3.0 mg for 12 weeks (until week 68).

- **Liraglutide 3.0mg (week0-56)/Liraglutide Placebo (week56-68) (Experimental):**
  Arm description:
  Drug: placebo
  Subject with no pre-diabetes at screening, receiving liraglutide 3.0 mg subcutaneous (under the skin) injection once daily for 56 weeks. Subjects completing 56 weeks are re-randomised to receive liraglutide placebo for 12 weeks (until week 68).

- **Liraglutide Placebo, no Pre-diabetes (Placebo Comparator):**
  Arm description:
  Drug: placebo
  Subject with no pre-diabetes at screening, receiving liraglutide 3.0 mg subcutaneous (under the skin) injection once daily for 56 weeks. Subjects completing 56 weeks are re-randomised to receive liraglutide placebo for 12 weeks (until week 68).

- **Liraglutide 3.0mg, Pre-diabetes (Experimental):**
  Arm description:
  Drug: liraglutide
  Liraglutide 3.0 mg, subcutaneous (under the skin) injection once daily for 160 weeks.

- **Liraglutide Placebo, Pre-diabetes (Placebo Comparator):**
  Arm description:
  Drug: placebo
  Liraglutide placebo, subcutaneous (under the skin) injection once daily for 160 weeks.

<table>
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<th>Trial status</th>
<th>No. of trial participants</th>
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<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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<table>
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<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>Informed consent obtained</td>
<td>Known type 1 or type 2 diabetes</td>
</tr>
<tr>
<td>Body Mass Index (BMI) of 30.0 kg/m^2 or</td>
<td>Glycosylated haemoglobin (HbA1c) of 6.5 %</td>
</tr>
<tr>
<td>above</td>
<td>or above (Screening visit 1) or FPG of 126</td>
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<tr>
<td>Body Mass Index (BMI) of 27 kg/m^2 or</td>
<td>mg/dL (7 mmol/L) or above (Screening visit</td>
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<td>above in the presence of co-morbidities</td>
<td>2) or 2 hour post-challenge (OGTT) plasma</td>
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<tr>
<td>treated or untreated dyslipidemia and/or hypertension</td>
<td>glucose of 200 mg/dL (11.1 mmol/L) or above (Screening visit 2)</td>
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<tr>
<td>Stable body weight</td>
<td>Screening calcitonin of 50 ng/L or above</td>
</tr>
<tr>
<td>Preceding failed dietary effort</td>
<td>Family or personal history of multiple endocrine neoplasia type 2 (MEN2) or familial medullary thyroid carcinoma (FMTC)</td>
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<tr>
<td></td>
<td>Personal history of non-familial medullary thyroid carcinoma</td>
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<tr>
<td></td>
<td>History of acute or chronic pancreatitis</td>
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<td></td>
<td>Obesity induced by drug treatment</td>
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<td></td>
<td>Use of approved weight lowering pharmacotherapy</td>
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<td></td>
<td>Previous surgical treatment of obesity</td>
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<td></td>
<td>History of major depressive disorder or suicide attempt</td>
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<td></td>
<td>Uncontrolled hypertension (systolic blood pressure of 160 mmHg or above and/or diastolic blood pressure of 100 mmHg or above)</td>
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</table>

### Trial type
**Interventional**

### Trial design
**Purpose:** Treatment  
**Allocation:** Randomized  
**Masking:** Double Blind  
**Control:** Placebo Control  
**Assignment:** Parallel Assignment

#### Primary outcome
- **Change from Baseline in Fasting Body Weight**  
  Time frame: Week 0, Week 56  
- **Proportion of Subjects Losing at Least 5% of Baseline Fasting Body Weight**  
  Time frame: At Week 56  
- **Proportion of Subjects Losing More Than 10% of Baseline Fasting Body Weight**  
  Time frame: At 56 weeks  
- **Proportion of Subjects With Onset of Type 2 Diabetes**  
  Time frame: At 160 weeks

#### Secondary outcome(s)
- **Change From Baseline in Waist Circumference (cm)**  
  Time frame: Week 0, Week 56  
- **Change From Baseline in Waist Circumference (Subjects With Pre-diabetes at Baseline)**  
  Time frame: Week 0, week 160  
- **Pre-diabetes Status After 56 Weeks of Treatment**  
  Time frame: Week 0, Week 56  
- **Pre-diabetes Status in Subject With Pre-diabetes at Baseline After 160 Weeks of Treatment**  
  Time frame: Week 0, week 160  
- **Mean Change From Baseline in Fasting Body Weight (Subjects With Pre-diabetes at Baseline)**  
  Time frame: Week 0, week 160

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• Proportion of Subjects Losing at Least 5% and Proportion of Subjects Losing More Than 10% of Baseline Fasting Body Weight (Subjects With Pre-diabetes at Baseline)  
  Time frame: At 160 weeks  
• Change From Week 56 in Fasting Body Weight (%) (Re-randomised Subjects With No Pre-diabetes)  
  Time frame: Week 56, Week 68  
• Change From Baseline in Fasting Body Weight (%) (Re-randomised Subjects With No Pre-diabetes)  
  Time frame: Week 0, Week 68

**Participating countries**  
Argentina: Suspended  
Australia: Completed  
Austria: Completed/Suspended  
Belgium: Completed/Suspended  
Brazil: Completed/Suspended  
Canada: Completed/Suspended  
Denmark: Completed  
Finland: Completed  
Former Serbia and Montenegro: Suspended  
France: Completed/Suspended  
Germany: Completed/Suspended  
Hong Kong: Completed  
Hungary: Completed/Suspended  
India: Completed/Suspended  
Ireland: Completed/Suspended  
Israel: Completed/Suspended  
Italy: Completed/Suspended  
Mexico: Completed/Suspended  
Netherlands: Completed/Suspended  
Norway: Completed/Suspended  
Poland: Completed/Suspended  
Russian Federation: Completed/Suspended  
Serbia: Completed  
South Africa: Completed  
Spain: Completed  
Switzerland: Completed  
Turkey: Completed/Suspended  
United Kingdom: Completed/Suspended  
United States: Completed/Suspended

**Central contact information**

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

**Labeling Information**
- EU:
- US: [Link to US labeling information](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/)

Information provided by Novo Nordisk A/S
PDF generation date: 10.Oct.2017

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