The Effect of Liraglutide on Endothelial Function in Subjects with Type 2 Diabetes Mellitus

This trial is conducted in the United States of America (USA). The purpose of the trial is to assess the effect of liraglutide on forearm blood flow in subjects with type 2 diabetes who are on diet and lifestyle changes or treated with metformin alone.

Scientific Title
The Effect of Liraglutide on Endothelial Function in Subjects with Type 2 Diabetes Mellitus: A 12-week randomized, double-blind, placebo-controlled, parallel-group, single-center trial with an open-label glimepiride arm

<table>
<thead>
<tr>
<th>Condition</th>
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<tbody>
<tr>
<td>Diabetes</td>
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<tr>
<td>Diabetes Mellitus, Type 2</td>
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<table>
<thead>
<tr>
<th>Trial IDs and acronym(s)</th>
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<tbody>
<tr>
<td>Novo Nordisk Trial ID</td>
<td></td>
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<tr>
<td>NN2211-1799</td>
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<tr>
<td>Clinical Trials.gov Registration</td>
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<tr>
<td>NCT00620282</td>
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<tr>
<td>Other Identifier(s)</td>
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<table>
<thead>
<tr>
<th>Trial dates</th>
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<tbody>
<tr>
<td>Primary completion date: 20.May.2010</td>
<td></td>
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<tr>
<td>Completion date: 20.May.2010</td>
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<table>
<thead>
<tr>
<th>Trial phase</th>
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<tbody>
<tr>
<td>Phase 3</td>
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<thead>
<tr>
<th>Treatment</th>
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<tbody>
<tr>
<td>liraglutide</td>
<td></td>
</tr>
<tr>
<td>placebo</td>
<td></td>
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<tr>
<td>glimepiride</td>
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Arm Information with Assigned Treatment
No. of arms: 3
• Lira 1.8 (Experimental):
  Arm description: Liraglutide 1.8 mg administered subcutaneously, once-daily, weeks 0-12 (100 uL/day, week 1; 200 uL/day, week 2; 300 uL/day, week 3-12)
  Drug: liraglutide
  Stepwise dose increase, s.c. (under the skin) injection, once daily
• Placebo (Placebo Comparator):
  Arm description: Placebo administered subcutaneously, once-daily, weeks 0-12 (100 uL/day, week 1; 200 uL/day, week 2; 300 uL/day, week 3-12)
  Drug: placebo
  Liraglutide placebo, stepwise dose increase, s.c. (under the skin) injection, once daily

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http://www.novonordisk-trials.com
Glimepiride (Active Comparator):
Arm description: Glimepiride 4 mg administered orally, once-daily, open-label, weeks 0-12
Drug: glimepiride
Tablets, 1 - 4 mg daily

<table>
<thead>
<tr>
<th>Trial status</th>
<th>No. of trial participants</th>
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<tbody>
<tr>
<td>Completed</td>
<td>49</td>
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<table>
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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>40 years to 70 years</td>
<td>Both</td>
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<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tr>
<td>• Type 2 diabetes</td>
<td>• Previous treatment with insulin (except for short term treatment with insulin in connection with intercurrent illness, at the discretion of the Investigator)</td>
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<td>• Diet and lifestyle changes or metformin monotherapy for at least three months</td>
<td>• Previous treatment with glucagon-like peptide-1 (GLP-1) analogues/mimetics, including treatment in a clinical trial</td>
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<tr>
<td>• HbA1c (glycosylated haemoglobin) 6.5-9.0% (both inclusive)</td>
<td>• Treatment with any oral hypoglycaemic agents other than metformin in a period of 3 months prior to screening</td>
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<tr>
<td>• Body Mass Index (BMI) less than or equal to 40 kg/m^2</td>
<td>• Current smoker or history of smoking within 6 months prior to screening</td>
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http://www.novonordisk-trials.com
<table>
<thead>
<tr>
<th>Trial type</th>
<th>Interventional</th>
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<tbody>
<tr>
<td>Trial design</td>
<td>Purpose: Treatment</td>
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<tr>
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<td>Allocation: Randomized</td>
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<td>Masking: Double Blind</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**
- Change in Acetylcholine (ACh)-mediated forearm blood flow (FBF)
  Time frame: week 0, week 12

**Secondary outcome(s)**
- Change in sodium nitroprusside (SNP)-mediated forearm blood flow (FBF)
  Time frame: week 0, week 12
- Change in HbA1c (Glycosylated haemoglobin A1c)
  Time frame: week 0, week 12
- Change in Fasting Plasma Glucose (FPG)
  Time frame: week 0, week 12
- Change in Mean Postprandial Glucose (PPG) Based on Self-measured 7-point plasma glucose profiles
  Time frame: week 0, week 12
- Change in Body Weight
  Time frame: week 0, week 12
- Fasting lipid profile - Change in Total Cholesterol (TC)
  Time frame: week 0, week 12
- Fasting lipid profile - Change in LDL-C
  Time frame: week 0, week 12
- Fasting lipid profile - Change in HDL-C
  Time frame: week 0, week 12
- Fasting lipid profile - Change in Triglycerides (TG)
  Time frame: week 0, week 12
- Biomarkers of cardiovascular risk - Change in TNF-alpha
  Time frame: week 0, week 12
- Haematology and biochemistry tests - Number of subjects with Blood Urea Nitrogen (BUN) values outside reference range
  Time frame: week 0, week 12
- Haematology and biochemistry tests - Number of subjects with Creatinine values outside reference range
  Time frame: week 0, week 12
- Number of Hypoglycaemic Episodes
  Time frame: weeks 0-12

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http://www.novonordisk-trials.com
**Participating countries**  
United States: Completed

**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:**
  

- **US:** http://www.accessdata.fda.gov/scripts/cder/drugsatfda/

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