Liraglutide or insulin in real life usage in patients with diabetes mellitus type 2

This study is conducted in Europe. The intention of this health service research study is to obtain data from daily routine to evaluate the quality of life and the costs of the disease for patients with type 2 diabetes mellitus.

**Scientific Title**
Liraglutide or insulin in real life usage in patients with diabetes mellitus type 2

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**Study IDs and acronym(s)**

**Novo Nordisk Trial ID**
NN2211-3962

**Clinical Trials.gov Registration**
NCT01484262

**Other Identifier(s)**
Other Identifier: U1111-1123-5044

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

**Study dates**
Start date: 14.Nov.2011
Primary completion date: 31.Oct.2014

**Study status**
Completed

**Study phase**
N/A

**Treatment**
- liraglutide
- insulin

**Group Information with Assigned Treatment**
No. of groups: 2
- Liraglutide
  Arm description:
  Drug: liraglutide
  Patients will be treated according to routine clinical practice at the discretion of the treating physician according to current labelling.
- Any insulin
  Arm description:
  Drug: insulin
  Any insulin in any device available on the market may be used by patients as part of routine
clinical practice according to current labelling.

<table>
<thead>
<tr>
<th>No. of study participants</th>
<th>1344</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age eligible for study participation</td>
<td>18 years to 70 years</td>
</tr>
<tr>
<td>Genders eligible for study participation</td>
<td>Both</td>
</tr>
</tbody>
</table>

### Inclusion criteria
- Informed consent obtained before any study-related activities. (Study-related activities are any procedures related to recording of data according to the protocol)
- Patients willing and able to give signed consent on matching patient data with sick fund data
- Patients diagnosed with type 2 diabetes mellitus, currently treated with oral antidiabetic medication, who need treatment intensification with insulin or liraglutide (Victoza®) due to inadequate blood glucose control
- Patient is a member of the involved sick fund (AOK Plus)

### Exclusion criteria
- Known or suspected contra-indication to the relevant study product according to current SPC
- Previous participation in this study
- History of type 1 diabetes mellitus
- Previous insulin treatment excluding emergency administration (treatment duration up to a maximum of 3 days)
- Previous treatment with liraglutide
- History of diabetic gastroparesis, diabetic precoma or diabetic ketoacidosis
- Progressive fatal disease
- Any reason in judgement of the treating physician that precludes study participation e.g. lack of compliance, safety concerns, alcohol or drug abuse
- Patients without legal capacity

### Study type
Observational

### Study design
Observational Model: Cohort
- Time Perspective: Prospective
- Study population: Patients diagnosed with type 2 diabetes mellitus, currently treated with oral antidiabetics (OADs), who need treatment intensification with insulin or liraglutide due to inadequate blood glucose control.

### Primary outcome
- Diabetes-related quality of life assessed by ADDQoL (Audit of Diabetes-Dependent Quality of Life)
  - Time frame: At the end of the observational period (52 weeks)

### Secondary outcome(s)
- Total cost of patient's diseases
  - Time frame: At the end of the observational period (52 weeks)
- Total cost of patient education
  - Time frame: At the end of the observational period
Participating countries
Germany: Completed

Central contact information
Study sponsored by: Novo Nordisk A/S
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For studies conducted in the US: (+1) 866-867-7178

Labeling information
- EU:

Information provided by Novo Nordisk A/S
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