Observational, safety study of NovoNorm® (repaglinide) and insulin analogue combination therapy in type 2 diabetes in Korea

This trial is conducted in Asia.
The primary objective of this study is to evaluate the clinical safety profile during 26 weeks of NovoNorm® (repaglinide) and insulin analogue combination therapy in type 2 diabetes under normal clinical practice conditions in Korea while the secondary objective is to evaluate the safety and efficacy after 13 and 26 weeks of NovoNorm® and insulin analogue combination therapy in type 2 diabetes under normal clinical practice conditions in Korea.

Scientific Title
A 26-week, multicentre, open-labelled, non-randomised, non-interventional, observational, safety study of NovoNorm® (repaglinide) and insulin analogue combination therapy in type 2 diabetes in Korea

<table>
<thead>
<tr>
<th>Study IDs and acronym(s)</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novo Nordisk Trial ID</td>
<td>Diabetes</td>
</tr>
<tr>
<td>AGEE-3905</td>
<td>Diabetes Mellitus, Type 2</td>
</tr>
<tr>
<td>Clinical Trials.gov Registration</td>
<td></td>
</tr>
<tr>
<td>NCT01355718</td>
<td></td>
</tr>
<tr>
<td>Other Identifier(s)</td>
<td>Other Identifier: U1111-1119-9152</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study dates</th>
<th>Study status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start date: 05.Aug.2011</td>
<td>Completed</td>
</tr>
<tr>
<td>Primary completion date: 26.Mar.2013</td>
<td></td>
</tr>
<tr>
<td>Completion date: 26.Mar.2013</td>
<td></td>
</tr>
</tbody>
</table>

| Study phase | |
|-------------| |
| N/A | |

| Treatment | |
|-----------| |
| • repaglinide | |

| Group Information with Assigned Treatment | |
|-------------------------------------------| |
| No. of groups: 1 | |
| • Repaglinide | |
| Arm description: | |
| Drug: repaglinide | |
| The dosage and frequency, as well as later changes to either dose, frequency or add-on medication (if applicable), will be determined by the physician, according to the patient’s | |

Disclaimer:
This document contains information about clinical trials sponsored by Novo Nordisk. It is not intended to replace the advice of a healthcare professional and should not be construed as providing advice or making a recommendation. The information on this site should not be relied on as the basis for any decision or action. Only a physician can determine whether a specific product is correct for a particular patient. If you have questions regarding any information contained on this site you should consult a physician.

http://www.novonordisk-trials.com
### Inclusion criteria
- Informed consent obtained before any study-related activities. (Study-related activities are any procedure related to recording of data according to the protocol.)
- Patients with type 2 diabetes mellitus
- Patients who are currently treated with NovoNorm® alone or in combination with metformin or TZD
- Age: at least 18 years old
- Patients who will be prescribed with insulin analogue in addition to current NovoNorm® (with/without metformin/TZD) treatment at the discretion by the Physician

### Exclusion criteria
- Known or suspected allergy to study product(s) or related products
- Previous participation in this study. Participation is defined as screened
- Patients who have been treated with insulin preparations (including insulin analogues) previously
- Females of childbearing potential who are pregnant, breast-feeding or intend to become pregnant or are not using adequate contraceptive methods (adequate contraceptive measures as required by local law or practice)
- Patients who are unlikely to comply with protocol requirements, e.g. uncooperative attitude, inability to return for the final visit
- Any other disease or condition that the Physician feels would interfere with study participation or evaluation of results

### Study type
Observational

### Study design
Observational Model: Cohort
Time Perspective: Prospective

Study population: Patients who are currently treated with NovoNorm® alone or in combination with metformin or TZD (thiazolidinedione) and will be additionally prescribed with insulin analogue at the discretion of the physicians will be eligible for this study.

### Primary outcome
- Incidence of serious Adverse Drug Reactions (SADRs) including major (serious)

### Secondary outcome(s)
- Incidence of Adverse Drug Reactions (ADRs)
  Time frame: week 13 and 26
## Incidence of Adverse Events (AEs)
**Time frame:** week 13 and 26

## Incidence of Serious Adverse Event (SAEs)
**Time frame:** week 13 and 26

## Change in HbA1c
**Time frame:** after 13 and 26 weeks of NovoNorm® and insulin analogue combination therapy

### Participating countries
- **Korea, Republic of:** Completed

### Central contact information
- **Study sponsored by:** Novo Nordisk A/S
- **Contact:** clinicaltrials@novonordisk.com
- **For studies conducted in the US:** (+1) 866-867-7178

### Labeling information
- **EU:**

---

Information provided by Novo Nordisk A/S

PDF generation date: 24.Oct.2017