A trial investigating the efficacy and safety of insulin degludec in children and adolescents with type 1 diabetes mellitus

This trial is conducted in Africa, Asia, Europe and the United States of America (USA).
The aim of this trial is to investigate the efficacy and safety of insulin degludec in children and adolescents with type 1 diabetes mellitus.

**Scientific Title**
A 26-week, Multinational, Multi-centre, Open-Labelled, Randomised, Parallel, Efficacy and Safety Comparison of Insulin Degludec and Insulin Detemir in children and adolescents 1 to less than 18 years with type 1 Diabetes Mellitus on a basal-bolus regimen with insulin aspart as bolus insulin, followed by a 26-week extension investigating long term safety (BEGIN™: Young 1)

**Trial IDs and acronym(s)**
- **Novo Nordisk Trial ID**: NN1250-3561
- **Clinical Trials.gov Registration**: NCT01513473
- **Other Identifier(s)**:
  - EudraCT Number: 2011-003148-39
  - Other Identifier: P/44/2010
  - Other Identifier: U1111-1122-4758
  - BEGIN™

**Condition**
- Diabetes
- Diabetes Mellitus, Type 1

**Trial dates**
- Primary completion date: 30.Jul.2013
- Completion date: 30.Jul.2013

**Trial phase**
- Phase 3

**Treatment**
- insulin degludec
- insulin detemir
- insulin aspart

**Arm Information with Assigned Treatment**
- **No. of arms**: 2
- **Insulin Degludec + Insulin Aspart (Experimental)**:  
  - Arm description:
  - Drug: insulin degludec
  - Injected subcutaneously (under the skin) once daily. Dose individually adjusted.
Drug: insulin aspart
Injected subcutaneously (under the skin) as mealtime bolus insulin. Dose individually adjusted.

- Insulin Detemir + Insulin Aspart (Experimental):
  Arm description:
  Drug: insulin detemir
  Injected subcutaneously (under the skin) once or twice daily. Dose individually adjusted.
  Drug: insulin aspart
  Injected subcutaneously (under the skin) as mealtime bolus insulin. Dose individually adjusted.

<table>
<thead>
<tr>
<th>Trial status</th>
<th>No. of trial participants</th>
</tr>
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<tbody>
<tr>
<td>Completed</td>
<td>350</td>
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<table>
<thead>
<tr>
<th>Age eligible for trial participation</th>
<th>Genders eligible for trial participation</th>
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<tr>
<td>1 years to 17 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>• Informed consent, and child assent as age-appropriate, obtained before any trial-related activities (Trial-related activities are any procedure that would not have been performed during normal management of the subject). The parents or legal representative of the child must sign and date the Informed Consent Form according to local requirements. The child, if possible, parents or legal representative of the child must sign and date the Child Assent Form according to local requirements</td>
<td>• Known or suspected hypersensitivity to trial product(s) or related products</td>
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<td>• Male or female diagnosed with type 1 diabetes mellitus (T1DM) (based on clinical judgement and supported by laboratory analysis as per local guidelines)</td>
<td>• Previous participation in this trial. Participation is defined as randomisation</td>
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<td>• Ongoing daily treatment with insulin (any regimen) for at least 3 months prior to Visit 1 (screening). No OADs (oral anti-diabetic drugs) are allowed</td>
<td>• Girls who are pregnant, breastfeeding or intend to become pregnant</td>
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<td>• HbA1c (glycosylated haemoglobin) maximum 11%</td>
<td>• Girls who have had menarche and are not using adequate contraceptive measures according to local requirements</td>
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<table>
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<tr>
<th>Trial type</th>
<th>Trial design</th>
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<tr>
<td>Interventional</td>
<td>Purpose: Treatment</td>
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<td></td>
<td>Allocation: Randomized</td>
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### Primary outcome
- Change from baseline in HbA1c (glycosylated haemoglobin) (%) at 26 weeks (analysed by central laboratory)
  Time frame: Week 0, week 26

### Secondary outcome(s)
- Change from baseline in HbA1c (%) at 52 weeks (analysed by central laboratory)
  Time frame: Week 0, week 52
- Change from baseline in fasting blood glucose (FPG) at 26 weeks (analysed by central laboratory)
  Time frame: Week 0, week 26
- Change from baseline in fasting blood glucose (FPG) at 52 weeks (analysed by central laboratory)
  Time frame: Week 0, week 52
- Number of treatment emergent adverse events (TEAEs)
  Time frame: After 26 weeks and 52 weeks of treatment
- Number of hypoglycaemic episodes
  Time frame: After 26 weeks and 52 weeks of treatment
- Number of self-measured hyperglycaemia (episodes of PG above 11.1 mmol/L (200 mg/dL))
  Time frame: After 26 weeks and 52 weeks of treatment
- Number of episodes with self monitored blood ketones above 1.5 mmol (capillary blood ketone measurement to be performed if self-measured plasma glucose (SMPG) exceeds 14.0 mmol/l (250 mg/dL))
  Time frame: After 26 weeks and 52 weeks of treatment
- Steady-state plasma concentrations of insulin degludec and insulin detemir on three different visits (three different weeks) during the first 26 weeks of treatment
  Time frame: Between week 1 and week 26
- Insulin antibodies (insulin degludec specific, insulin detemir specific, insulin aspart specific and antibodies cross-reacting to human insulin)
  Time frame: After 52 weeks of treatment
Participating countries
Bulgaria: Completed
Finland: Completed
France: Completed
Germany: Completed/Suspended
Italy: Completed/Suspended
Japan: Completed
Macedonia, The Former Yugoslav Republic of: Completed
Netherlands: Completed
Russian Federation: Completed/Suspended
South Africa: Completed
United Kingdom: Completed/Suspended
United States: Completed/Suspended

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

Labeling information
- EU:

Information provided by Novo Nordisk A/S
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