**Glycemic control of biphasic insulin aspart 30 in type 2 diabetes**

This trial is conducted in Europe. The aim of this trial is to compare glycaemic control of biphasic insulin aspart 30 (BIAsp 30) alone or combined with insulin aspart (IAsp) in patients previously treated with conventional Biphasic Human Insulin 30/70.

**Scientific Title**
Comparison of Biphasic Insulin Aspart 30 twice daily and Biphasic Insulin Aspart 30 twice daily plus lunchtime injection of insulin aspart treatment efficiency in overall glycemic control and postprandial glycemic excursions.

A multi-center, randomized, open-label, two-armed parallel group trial in subjects with type 2 diabetes previously treated with conventional biphasic human insulin 30/70

<table>
<thead>
<tr>
<th>Trial IDs and acronym(s)</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novo Nordisk Trial ID</td>
<td>Diabetes</td>
</tr>
<tr>
<td>BIASP-1409</td>
<td>Diabetes Mellitus, Type 2</td>
</tr>
<tr>
<td>Clinical Trials.gov Registration</td>
<td></td>
</tr>
<tr>
<td>NCT01697631</td>
<td></td>
</tr>
<tr>
<td>Other Identifier(s)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trial dates</th>
<th>Trial phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start date: 22.Jul.2002</td>
<td>Phase 4</td>
</tr>
<tr>
<td>Primary completion date: 24.Apr.2003</td>
<td></td>
</tr>
<tr>
<td>Completion date: 24.Apr.2003</td>
<td></td>
</tr>
</tbody>
</table>

**Treatment**
- biphasic insulin aspart 30
- insulin aspart

**Arm Information with Assigned Treatment**
No. of arms: 2
- BIAsp (Experimental):
  Arm description:
  Drug: biphasic insulin aspart 30
  Administrated subcutaneously (s.c., under the skin) at breakfast and evening main meals
- Insulin aspart (Experimental):
  Arm description:
  Drug: biphasic insulin aspart 30
  Administrated subcutaneously (s.c., under the skin) at breakfast and evening main meals

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
**Drug:** insulin aspart  
Administered subcutaneously (s.c., under the skin) before lunch

<table>
<thead>
<tr>
<th><strong>Trial status</strong></th>
<th><strong>No. of trial participants</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed</td>
<td>131</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Age eligible for trial participation</strong></th>
<th><strong>Genders eligible for trial participation</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>18 years and above</td>
<td>Both</td>
</tr>
</tbody>
</table>

**Inclusion criteria**
- Type 2 diabetes  
- Current treatment with conventional biphasic human insulin 30/70 b.i.d. (twice daily) for at least 3 months  
- HbA1c (glycosylated haemoglobin) equal to or below 12%  
- Willing and able to perform self blood glucose monitoring (SMBG)

**Exclusion criteria**
- History of drug or alcohol dependence  
- Mental incapacity, unwillingness or language barriers precluding adequate understanding or co-operation  
- Previous participation in this trial  
- Receipt of any investigational drug within the last month prior to this trial  
- Known or suspected allergy to trial products or related products

**Trial type**
Interventional

**Trial design**
- Purpose: Treatment  
- Allocation: Randomized  
- Masking: Control: Active Control  
- Assignment: Parallel Assignment

<table>
<thead>
<tr>
<th><strong>Primary outcome</strong></th>
<th><strong>Secondary outcome(s)</strong></th>
</tr>
</thead>
</table>
| HbA1c (glycosylated haemoglobin) | 7-point blood glucose profile  
|                      | Correlation of endpoint HbA1c with baseline BMI (body mass index) and HbA1c with treatment mode stratification  
|                      | Incidence of adverse events  
|                      | Hypoglycaemic episodes (minor, major or nocturnal) |

**Participating countries**
Poland: 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**

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
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.