Efficacy and safety of insulin aspart vs. human insulin during pregnancy by women with type 1 diabetes

This trial was conducted in Europe, Middle East, North America and South America.
The aim of this trial was to compare the use of an intensified insulin treatment with insulin aspart (NovoRapid®) versus human insulin (Actrapid®) in pregnancy.

Scientific Title
A randomised, parallel-group, open-label, multinational trial comparing the safety and efficacy of insulin aspart (NovoRapid®) versus human insulin (Actrapid®), used in a multiple injection regimen, in the treatment of pregnant women with type 1 diabetes, focusing on maternal hypoglycaemia and pregnancy outcomes

<table>
<thead>
<tr>
<th>Trial IDs and acronym(s)</th>
<th>Condition</th>
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<tbody>
<tr>
<td>Novo Nordisk Trial ID</td>
<td>Diabetes</td>
</tr>
<tr>
<td>ANA-1474</td>
<td>Diabetes Mellitus, Type 1</td>
</tr>
<tr>
<td>Clinical Trials.gov Registration</td>
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<td>NCT00365170</td>
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<table>
<thead>
<tr>
<th>Other Identifier(s)</th>
<th>Trial phase</th>
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<tbody>
<tr>
<td></td>
<td>Phase 4</td>
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<table>
<thead>
<tr>
<th>Trial dates</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start date: 18.Sep.2002</td>
<td>• human insulin</td>
</tr>
<tr>
<td>Primary completion date: 14.Apr.2005</td>
<td>• insulin aspart</td>
</tr>
<tr>
<td>Completion date: 14.Apr.2005</td>
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<table>
<thead>
<tr>
<th>Arm Information with Assigned Treatment</th>
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<tbody>
<tr>
<td>No. of arms: Not applicable</td>
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<table>
<thead>
<tr>
<th>Trial status</th>
<th>No. of trial participants</th>
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<tbody>
<tr>
<td>Completed</td>
<td>419</td>
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<tr>
<th>Age eligible for trial participation</th>
<th>Genders eligible for trial participation</th>
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<tbody>
<tr>
<td>18 years and above</td>
<td>Female</td>
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<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>• Type 1 diabetes</td>
<td>• Previous birth of child with a major</td>
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</tbody>
</table>
- Treated with insulin for at least 12 months
- Either plan to become pregnant in the immediate future, willing to undertake pre pregnancy counselling, and has a screening HbA1c lesser than or equal to 12.0%, or
- Pregnant with normal singleton pregnancy, gestational age for at least 10 weeks at the time of randomisation, confirmed by ultrasound scan.

- congenital malformation
- More than 2 previous multiple miscarriages or stillbirths
- Severe hyperemesis gravidarum, requiring hospitalisation, according to Investigator judgement
- Subjects being treated for infertility
- Proliferative retinopathy or maculopathy requiring acute treatment
- Drug or alcohol abuse
- Impaired renal, hepatic or cardiac function

**Trial type**
Interventional

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

**Primary outcome**
- Relative risk of major maternal hypoglycaemia
  Time frame: after 24 hours

**Secondary outcome(s)**
- Relative risk of major and minor hypoglycaemia
- Diabetic complications
- Obstetric complications
- Other Adverse Events

**Participating countries**
Argentina: Completed/Suspended
Austria: Completed/Suspended
Bulgaria: Completed
Canada: Completed/Suspended
Croatia: Completed
Denmark: Completed
Finland: Completed/Suspended
France: Completed/Suspended
Germany: Completed
Greece: Completed
Ireland: Completed
Israel: Completed/Suspended
Netherlands: Completed/Suspended
Norway: Completed/Suspended
Poland: Completed
Russian Federation: Completed
Spain: Completed
United Kingdom: Completed/Suspended

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http://www.novonordisk-trials.com
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

Information provided by Novo Nordisk A/S
PDF generation date: 16.Oct.2017

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