Observational study of NovoPen Echo® on safety and treatment satisfaction in children and adolescents with type 1 diabetes

This study is conducted in Asia, Europe and North America. The aim of this observational study is to evaluate the safety of NovoPen Echo® by collecting safety information (incidence of technical complaints related to adverse reactions). Study duration: 12-18 weeks.

Scientific Title
A multicentre, observational study of NovoPen Echo® on safety and treatment satisfaction of insulin therapy in children and adolescents with diabetes mellitus

<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>PDS328-3741</td>
<td>- Diabetes Mellitus, Type 1</td>
</tr>
<tr>
<td>Clinical Trials.gov Registration</td>
<td>- Delivery systems</td>
</tr>
<tr>
<td>NCT01180530</td>
<td></td>
</tr>
<tr>
<td>Other Identifier(s)</td>
<td></td>
</tr>
<tr>
<td>Other Identifier: U1111-1113-5037</td>
<td></td>
</tr>
<tr>
<td>REMIND™</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study dates</th>
<th>Study status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start date: 12.Oct.2010</td>
<td>Completed</td>
</tr>
<tr>
<td>Primary completion date: 31.Mar.2011</td>
<td></td>
</tr>
<tr>
<td>Completion date: 31.Mar.2011</td>
<td></td>
</tr>
</tbody>
</table>

Study phase
N/A

Treatment
- NovoPen Echo®

Group Information with Assigned Treatment
No. of groups: 1
- A
  - Arm description:
    - Device: NovoPen Echo®
    - Prescribed insulin treatment delivered by NovoPen Echo®

No. of study participants
358

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.
### Inclusion criteria
- Children/adolescents with type 1 diabetes mellitus
- After the participating physician's decision has been made to initiate treatment with NovoPen Echo®, any patient who meets all the inclusion criteria and does not meet any of the exclusion criteria, is eligible to participate
- Use of insulin pen or syringes for at least 12 months

### Exclusion criteria
- Insulin pump or Insuflon® users
- Any disease or condition in children/adolescents which might interfere with the study at the individual physician’s discretion

### Study type
Observational

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

Study population: Any child or adolescent with type 1 diabetes who has just started using NovoPen Echo® is eligible. The selection of the patients will be at discretion of the individual physician.

### Primary outcome
- The incidence of technical complaints related to adverse reactions
  Time frame: after 12-18 weeks (end of study)

### Secondary outcome(s)
N/A

### Participating countries
- Canada: Completed
- Finland: Completed
- Israel: Completed
- Sweden: 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: No EMA specific device labelling information available

---

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.