Efficacy and safety of recombinant human growth hormone on height velocity in subjects with idiopathic short stature

This trial is conducted in Asia.
The aim of this trial is to evaluate the efficacy and safety of recombinant human growth hormone (hGH) in subjects with idiopathic short stature in Korea.

Scientific Title
A 12-month, open-labelled, randomised, parallel-group, multi-centre, interventional trial to evaluate the efficacy and safety of recombinant human growth hormone (hGH) (Norditropin® Nordilet®) therapy on height velocity (Ht-V) in patients with idiopathic short stature in Korea

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**Trial IDs and acronym(s)**

Novo Nordisk Trial ID
GH-3899

Clinical Trials.gov Registration
NCT01778023

Other Identifier(s)
EudraCT Number: 2015-002613-30
Other Identifier: U1111-1125-4790

**Condition**
Idiopathic Short Stature
Growth disorder

**Trial dates**
Start date: 17.Jan.2013
Primary completion date: 17.Dec.2014
Completion date: 17.Dec.2014

**Trial phase**
Phase 3

**Treatment**
- somatropin

**Arm Information with Assigned Treatment**
No. of arms: 2
- hGH: 12 months treatment (Experimental):
  Arm description:
  Drug: somatropin
  A weekly dosage of 0.469 mg of somatropin per kg of body weight per week will be injected subcutaneously (under the skin) in the evening in 7 days per week.
- hGH: 6 month un-treatment + 6 month treatment (Active Comparator):
  Arm description:
  Drug: somatropin
  A weekly dosage of 0.469 mg of somatropin per kg of body weight per week will be injected

Disclaimer:
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http://www.novonordisk-trials.com
subcutaneously (under the skin) in the evening in 7 days per week.

<table>
<thead>
<tr>
<th>Trial status</th>
<th>No. of trial participants</th>
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<tbody>
<tr>
<td>Completed</td>
<td>54</td>
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<table>
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<tr>
<th>Age eligible for trial participation</th>
<th>Genders eligible for trial participation</th>
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<td>4 years to 11 years</td>
<td>Both</td>
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**Inclusion criteria**
- Informed consent obtained from subject’s parents or legally acceptable representative before any trial-related activities. (Trial-related activities are any procedure that would not have been performed during normal management of the subject.)
- Pre-pubertal status (males aged from 4 to 11 [both inclusive], females aged from 4 to 9 [both inclusive]): an absence of breast development in females (Tanner 1 only) and testicular volume below 4 mL in males
- Growth hormone level above 10 ng/mL following a stimulation test (test result within 6 months from screening can be used)
- Height below 3 percentile
- Bone age below or equal to 12 year
- Epiphyses confirmed as open in patients at least 10 years or more of age

**Exclusion criteria**
- Known presence of one or more pituitary hormone deficiencies (ACTH [adrenocorticotropic hormone], ADH [antidiuretic hormone], FSH [follicle-stimulating hormone], LH [luteinising hormone], TSH [thyroid-stimulating hormone])
- Known primary hypothyroidism, adrenal insufficiency or hypogonadism (treated or untreated)
- Specific types of growth failure including, but not limited to, known chromosomal abnormalities associated with growth failure and altered sensitivity to growth hormone
- Bone age is advanced over chronological age more than 3 years
- Active malignancy, CNS (central nervous system) trauma, active chemotherapy or radiation therapy for neoplasia
- Prior history of intracranial hypertension
- Hypertrophic cardiomyopathy

**Trial type**
Interventional

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

**Primary outcome**
- Height velocity (Ht-V)
  Time frame: After 6 months of treatment

**Secondary outcome(s)**
- Change in Ht-SDS (height standard deviation score)
  Time frame: After 6 months of treatment
- Change in IGF related factors: IGF-I (insulin-like growth factor-I)
  Time frame: After 6 months of treatment
- Change in IGF related factors: IGFBP-3 (insulin-like growth factor binding protein-3)  
  Time frame: After 6 months of treatment.
- Change in bone age  
  Time frame: After 6 months of treatment.
- Occurrence of Adverse events  
  Time frame: Throughout the trial (12 months)
- Ht-V (height velocity)  
  Time frame: At the first 6 months and the last 6 months in group A

**Participating countries**
Korea, Republic of: 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**
N/A

Information provided by Novo Nordisk A/S  
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