BEGIN: YOUNG 1, trial id: NN1250-3561. A clinical trial investigating the efficacy and safety of insulin degludec in children and adolescents with type 1 diabetes mellitus.

Published: 21-10-2011
Last updated: 30-04-2024

Primary objective: to confirm the efficacy of insulin degludec administered once daily plus mealtime insulin aspart in controlling glycaemia with respect to change from baseline in HbA1c after 26 weeks of treatment. Secundary objective: to compare...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON37499

Source
ToetsingOnline

Brief title
NN1250-3561

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes mellitus type 1, insulin dependent diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Novo Nordisk
Source(s) of monetary or material Support: Novo Nordisk (industrie)

Intervention

Keyword: Adolescents, Children, Diabetes type 1, Insulin degludec

Outcome measures

Primary outcome

Change from baseline in HbA1c after 26 weeks of treatment.

Secondary outcome

Efficacy: change from baseline in fasting plasma glucose after 26 weeks of

treatment, several parameters from 8-point profile and 4-point profile

Safety: amongst others; number of hypo- and hyperglycaemic episodes in both

treatment arms, insulin antibody measurement and laboratory parameters

(hematology, biochemistry and lipids).

Pharmacokinetics: insulin degludec and insulin detemir plasmaconcentration.

Study description

Background summary

This trial is being conducted in agreement with the EMA Paediatric Committee (PDCO) to investigate the efficacy and safety of insulin degludec in children and adolescents with type 1 diabetes. Although several insulin products are available on the market and can be used by paediatric patients, there is still a need for refinement of these products to more closely resemble the physiological action profile of endogenous insulin and to reduce unwanted side effects. Based on available clinical data insulin degludec has shown to have a flat profile and a prolonged action profile compared to the insulin products currently on the market.

Study objective

Primary objective: to confirm the efficacy of insulin degludec administered once daily plus mealtime insulin aspart in controlling glycaemia with respect to change from baseline in HbA1c after 26 weeks of treatment.

Secundary objective: to compare the efficacy and safety between the two treatment arms after 26 weeks of treatment in terms of other parameters of glycaemic control, safety and pharmacokinetics.

Study design

This is an open-labelled, randomised trial with 2 parallel groups: 1) insulin degludec and 2) insulin detemir, both in combination with insulin aspart. Subjects will be randomised 1:1 in one of the two groups. The treatment period is 26 weeks followed by a wash-out week.

Intervention

The intervention is a daily injection with insulin degludec or once to twice daily injection with insulin detemir. In both groups subject should also inject themselves before each meal with insulin aspart. During the wash-out period subjects take one to twice daily injections with insulin NPH and injections of insulin aspart before each meal.

Study burden and risks

It is possible that blooddrawals can cause haemorrhages or discomfort. Intensification of insulin treatment can lead to hypoglycaemic episodes. Subjects on insulin degludec, can experience that their hypo's lasts longer due to the prolonged action of insulin degludec.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

-type 1 diabetes mellitus
-age: 1 to less than 18 years of age
-ongoing daily treatment with insulin for at least three months
-HbA1c of 11% or below

Exclusion criteria

-known or suspected hypersensitivity to trial product
-known hypoglycaemic unawareness
-more than 1 ketoacidosis requiring hospitalisation within the last 3 months

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-02-2012
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Insulatard
Generic name:	Insulin human
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Insulin degludec
Generic name:	Insulin degludec
Product type:	Medicine
Brand name:	Levemir
Generic name:	Insulin detemir
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	NovoRapid
Generic name:	Insulin aspart
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-10-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-11-2011

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-12-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-01-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-01-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-04-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-05-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-07-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-003148-39-NL
CCMO	NL38149.060.11