Het effect van pegvisomant op kwaliteit van leven en insuline gevoeligheid. The effect of pegvisomant on quality of life and insulin sensitivity

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24622

Source
Nationaal Trial Register

Brief title
PEQoL

Health condition

GH IGF1, pituitary tumor, Acromegaly

Groeihormoon IGF1 hypofyse tumor Acromegalie

Sponsors and support

Primary sponsor: Dept. of Medicine, Erasmus University MC
Department of Endocrinology and Metabolism,
Leiden University Medical Center
Source(s) of monetary or material Support: Pfizer will provide the Placebo and Pegvisomant

Intervention

Outcome measures

Primary outcome

Primary Efficacy Variables:

Change in the Quality of Life over 16 weeks. Assessed by AcroQoL and PASQ.

Secondary outcome

Safety Variables:

Adverse event and local tolerance information recorded at any time throughout the study.

Vital signs recorded at visits V1, V2, V3, V4, V5 & V6.

Physical examination recorded at visits V1, V2, V4 & V6.

Cardiac- sonography and glucose tolerance based on oral glucose tolerance test measured at visits V1 and V6. HbA1C will be measure at visits V1, V2, V3, V4, V5 & V6.
Laboratory tests: QoL, standard hematology and biochemistry plus, IGF-I levels, GH levels, PEG-levels, ALT, AST, GGT, AP, PT and total bilirubin will be measured at visits V1, V2, V4, V5 and V6.

Pituitary MRI prior and at the end of the study.

Pharmacokinetic Variables:

Pegvisomant serum levels will be assessed in all patients at visits V2, V4, V6.

Study description

Background summary

Primary Study Objective:

To assess the efficacy and safety of the co-administration of low-dose pegvisomant (40 mg, administered via subcutaneous injection given once a week) and long-acting somatostatin analogs (administered once monthly) on the Quality of Life over 16 weeks in 60 acromegalic patients.
The primary endpoint will be the change in the AcroQol-physical score at the end of the treatment period.

Secondary Study Objectives:

To assess the effect of low-dose pegvisomant co-administration on:

Total body water / body weight.

Blood pressure

HbA1c

BNP levels

Ring-size

IGF-I levels

Safety based on:

Adverse events, clinical examination, vital signs

Glucose tolerance

Standard hematology and biochemistry, including liver function tests

This will be a multicentre, randomized double blind study.

Patients eligible for the study will continue their usual dose and frequency of administration of a long-acting somatostatin analog. They will start using low-dose pegvisomant as add-on, or placebo as add-on. The dose of pegvisomant will be fixed.
Acromegalic patients will be recruited in order to ensure 60 evaluable patients will enter the co-treatment period. All subjects should previously be treated with somatostatin analogues during which treatments their IGF-I levels should have normalized.

Inclusion criteria:

All patients must fulfill the following:

At the screening visit,

Provision of written informed consent prior to any study related procedures.

Male or female age ≥ 18 years.

The patient must have had documentation supporting the diagnosis of acromegaly based on elevated GH and/or IGF-1 levels.

The patient is treated with lanreotide Autogel or octreotide LAR for at least 6 months and has

a serum IGF-1 level above the 60th percentile and below ULN, 28 days after the last injection.

Exclusion Criteria

Patients will not be included in the study if he/she:

Has undergone pituitary surgery or radiotherapy within 6 months prior to study entry.

If patients have an optimal QoL (100%) assessed by the AcroQoL physical dimension, they cannot enter the study.
It is anticipated that the patient will receive pituitary surgery or radiotherapy during the study.

Has a history of hypersensitivity to lanreotide, octreotide or pegvisomant or drugs with a similar chemical structure.
Has already been treated with a somatostatin analogue associated with pegvisomant.

Has received a dopamine agonist within 6 weeks prior to study entry.

Has been treated with any unlicensed drug within the last 30 days before study entry.
Has abnormal hepatic function at study entry (defined as AST, ALT, gGT, alkaline phosphatase, or total bilirubin above 2 ULN).

Is at risk of pregnancy or is lactating. Females of childbearing potential must provide a negative pregnancy test within 5 days before the start of the study and must be using contraception. Non-childbearing potential is defined as post-menopause for at least one year, surgical sterilization or hysterectomy at least three months before the start of the study.

Has a history of, or known current, problems with alcohol or drug abuse.

Has a mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study, and/or evidence of an uncooperative attitude.

Has abnormal baseline findings, any other medical condition(s) or laboratory findings that, in the opinion of the investigator, might jeopardize the subject’s safety or decrease the chance of obtaining satisfactory data needed to achieve the objective(s) of the study.

Renal insufficiency, clearance < 60 ml/min.
Participation in a clinical trail in the last 12 months.

Study Product:

Pegvisomant or placebo will be administered via subcutaneous injections once weekly. Both are powders and need to be solved in sterile water. The vials are equal for the placebo and Pegvisomant, as well are the water vials

Study objective

Normal IGF1 levels during somatostatin analogue treatment will not normalize Growth hormone (GH) levels at the tisuue levels. By adding Pegviomant (GH antagonist) we will block this GH effect and improve the typical residual complaints of the patients and improve the Quality of life.

Study design

Screening visit (V1):

Singed informed consent

QoL assessment

vital signs

physical examination

BIA

ECG

standard haematology

biochemistry plus, ALT, AST, GGT, AP, PT, total bilirubin

IGF1

GH

fasting glucose

HBA1C

BNP

Pregnancy test is applicable

OGTT and cardiac sonography will be preformed if patients are eligible between V1 and V2

Apotheek zorg will be notified to visit patient. Physician will check if patient had contact with Apotheek zorg within 2 weeks after notification.

Visit 2 (V2):

vital signs

physical examination

BIA

ECG

standard haematology

biochemistry plus, ALT, AST, GGT, AP, PT, total bilirubin

IGF1

GH

fasting glucose

HBA1C

BNP

QoL assessment

Visit 3 (V3) & Visit 5 (V5)

vital signs

BIA

ECG

standard haematology

biochemistry plus, ALT, AST, GGT, AP, PT, total bilirubin

IGF1

GH

fasting glucose

HBA1C

BNP

Pegvisomant levels

QoL assessment

Empty vials collection

Visit 4 (V4)

vital signs

physical examination

BIA

ECG

standard haematology

biochemistry plus, ALT, AST, GGT, AP, PT, total bilirubin

IGF1

GH

fasting glucose

HBA1C

BNP

QoL assessment

Pegvisomant levels

Empty vials collection

End of study visit or visit 6 (V6)

vital signs

physical examination

BIA

ECG

standard haematology

biochemistry plus, ALT, AST, GGT, AP, PT, total bilirubin

IGF1

GH

fasting glucose

HBA1C

BNP

QoL assessment

Pegvisomant levels

Empty vials collection

OGTT and cardiac sonography will be preformed if patients are eligible between week 15 and 17.

Intervention

Study Product:

Pegvisomant or placebo will be administered via subcutaneous injections once weekly. Both are powders and need to be solved in sterile water. The vials are equal for the placebo and Pegvisomant, as well are the water vials

Contacts

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Eligibility criteria

Inclusion criteria

A written informed consent.
Male or female age ≥ 18 years. The patient must have had documentation supporting the diagnosis of acromegaly based on elevated GH and/or IGF1 levels.
The patient is treated with lanreotide Autogel or octreotide LAR for at least 6 months and has a serum IGF1 level above the 60th percentile and below 1.2 x ULN, 28 days after the last injection.

Exclusion criteria

Has undergone pituitary surgery or radiotherapy within 6 months prior to study entry.
If patients have an optimal QoL (100%) assessed by the AcroQoL physical dimension, they cannot enter the study.
It is anticipated that the patient will receive pituitary surgery or radiotherapy during the study.
Has a history of hypersensitivity to lanreotide, octreotide or pegvisomant or drugs with a similar chemical structure.
Has already been treated with a somatostatin analogue associated with pegvisomant.
Has received a dopamine agonist within 6 weeks prior to study entry.
Has been treated with any unlicensed drug within the last 30 days before study entry.
Has abnormal hepatic function at study entry (defined as AST, ALT, gGT, alkaline phosphatase, or total bilirubin above 2 ULN).
Is at risk of pregnancy or is lactating. Females of childbearing potential must provide a negative pregnancy test within 5 days before the start of the study and must be using contraception. Non-childbearing potential is defined as post-menopause for at least one year, surgical sterilization or hysterectomy at least three months before the start of the study.
Has a history of, or known current, problems with alcohol or drug abuse.
Has a mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study, and/or evidence of an uncooperative attitude.

Has abnormal baseline findings, any other medical condition(s) or laboratory findings that, in the opinion of the investigator, might jeopardize the subject’s safety or decrease the chance of obtaining satisfactory data needed to achieve the objective(s) of the study.
Renal insufficiency, clearance < 60 ml/min

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2013
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-08-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39522
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3935
NTR-old	NTR4103
CCMO	NL37992.078.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39522

Study results

Summary results
N/A