Pegvisomant-toevoeging bij patiënten met acromegalie: Effect op symptomen, kwaliteit van leven en insuline-gevoeligheid.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24812

Source
Nationaal Trial Register

Health condition

Acromegaly, pituitary disease, normal IGF1, somatostatin analogues, Pegvisomant

Sponsors and support

Primary sponsor: Erasmus University MC
Dept. of Medicine
PO Box 2040
3000 CA Rotterdam NL
Tel: +31 10 703 2862
Source(s) of monetary or material Support: Placebo and Pegvisomant will be supplied by Pfizer. Additional costs will paid by the department of internal medicine.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Insulin sensitivity after oral glucose loading.
and change in:

1. Total body water /body weight;

2. Blood pressure;

3. HbA1c;

4. BNP levels;

5. Ring-size;

6. IGF-I levels;

7. GH levels;

8. PEG-levels.

Study description

Background summary

Randomized double blind multi-centre study of the effects on low-dose pegvisomant treatment in acromegalic subjects in whom the IGF-I levels has been normalized by long-acting somatostatin analogs.

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: Quality of life and insuline sensitivity.

1. AcroQoL and PASQ;

2. Oral glucose loading;

3. Total body water / body weight;

4. Blood pressure;

5. HbA1c;

6. BNP levels;

7. Ring-size;

8. IGF-I levels;

9. Safety based on:

A. Adverse events, clinical examination, vital signs;

B. Glucose tolerance;

C. Standard hematology and biochemistry, including liver function tests.

Study objective

1. Addition of weekly pegvisomant administrations improves quality of life;

2. Addition of weekly pegvisomant administrations improves insulin sensitivity.

Study design

Efficacy will be assessed as change between prestudy visit and visit at 16 weeks.

Intervention

Weekly sc administration of Pegvisomant (40 mg) or placebo during 16 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

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

2. Male or female aged between 18 and 75 years inclusive;

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

4. 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

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

2. It is anticipated that the patient will receive pituitary surgery or radiotherapy during the study;

3. Has a history of hypersensitivity to lanreotide, octreotide or pegvisomant or drugs with a

similar chemical structure;

4. Has already been treated with a somatostatin analogue associated with pegvisomant;

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

6. Has been treated with any unlicensed drug within the last 30 days before study entry;

7. Has abnormal hepatic function at study entry (defined as AST, ALT, gGT, alkaline phosphatase, or total bilirubin above 2 ULN);

8. 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;

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

10. 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;

11. 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;

12. Renal insufficiency, clearance < 60 ml/min;

13. Participation in a clinical trial in the last 6 months.

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):	01-12-2011
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL2886
NTR-old	NTR3032
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Neggers SJ, van Aken MO, de Herder WW, Feelders RA, Janssen JA, Badia X, Webb SM, van der Lely AJ (2008) Quality of life in acromegalic patients during long-term somatostatin analog treatment with and without pegvisomant. The Journal of clinical endocrinology and metabolism 93 (10):3853-3859.

Biermasz NR, Pereira AM, Smit JW, Romijn JA, Roelfsema F (2005) Morbidity after long-term remission for acromegaly: persisting joint-related complaints cause reduced quality of life. The Journal of clinical endocrinology and metabolism 90 (5):2731-2739.
Bonapart IE, van Domburg R, ten Have SM, de Herder WW, Erdman RA, Janssen JA, van der Lely AJ (2005) The 'bio-assay' quality of life might be a better marker of disease activity in acromegalic patients than serum total IGF-I concentrations. European journal of endocrinology / European Federation of Endocrine Societies 152 (2):217-224.