A PROSPECTIVE, INTERNATIONAL, MULTI-CENTRIC, OPEN-LABEL STUDY TO ASSESS THE EFFICACY OF AN EXTENDED INJECTION INTERVAL SCHEDULE OF LANREOTIDE AUTOGEL 120 MG IN ACROMEGALIC SUBJECTS WHO ARE BIOCHEMICALLY CONTROLLED ON THE LONG TERM TREATMENT WITH OCTREOTIDE LAR 10 OR 20 MG

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The purpose of this study is to look at the effect of changing from monthly (4 weekly) injections of your usual treatment (octreotide LAR) to less frequent treatment (once every 6 or 8 weeks) with lanreotide Autogel 120 mg injections. The study…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Interventional

Summary

ID

NL-OMON38013

Source
ToetsingOnline

Brief title
LEAD - 214

Condition

- Hypothalamus and pituitary gland disorders

Synonym
Acromegaly, Gigantism

Research involving
Human

Sponsors and support

Primary sponsor: Ipsen Pharmaceuticals
Source(s) of monetary or material Support: Ipsen

Intervention

Keyword: acromegalic patients, Extended duration, Lanreotide Autogel, Switch

Outcome measures

Primary outcome

Primary Efficacy Endpoint(s) and Evaluation(s):

The primary efficacy endpoint will be the percentage of subjects having maintained their injection interval schedule of six weeks or increased their injection interval to eight weeks whilst keeping their normalised IGF 1 levels (age and sex adjusted) at study end at Week 48.

Secondary outcome

Secondary Efficacy Endpoints And Evaluations:

• Percentage of subjects with normalised IGF 1 levels (age and sex adjusted) at Week 24.

• Percentage of subjects having maintained an injection interval of six weeks or increasing their injection interval to eight weeks during Phase 2 of the study.

• Percentage of subjects who extend their injection interval to eight weeks during Phase 2 of the study, whilst maintaining normalised IGF 1 levels at Week 48.

• Mean change from baseline in IGF 1 values (expressed as % of ULN) at the end of the study (Week 48), overall and by injection interval.

• Treatment group (A, B or C) mean baseline IGF 1 levels (expressed as % of ULN) in subjects who maintained normalised IGF 1 values at Week 48. Comparisons will be made as follows: A versus B, A versus C, A versus (B+C) and B versus C.

• Mean baseline IGF 1 levels (expressed as % of ULN) in all groups (A, B and C) versus mean baseline IGF 1 levels (expressed as % of ULN) in subjects with uncontrolled IGF 1 levels at Week 24.

• Symptoms of acromegaly (headache, excessive perspiration, fatigue, soft tissue swelling and arthralgia) at baseline, Weeks 24 and 48.

• Mean changes from baseline in Quality of Life scores (AcroQoL* and SF 36) at Week 24 and Week 48. Results will be presented according to IGF 1 adjusted levels at each time point and according to the injection interval (during Phase 2 of the study).

• Serum GH levels at baseline, Weeks 24 and 48.

• The number and percentage of subjects with GH <=2.5 ng/mL at Weeks 24 and 48.

• Subject treatment schedule preference at Weeks 24 and 48. At Week 24, the preference will be assessed between Oct-LAR intramuscular injections every four weeks and lanreotide Autogel 120 mg subcutaneous injections every six weeks. At Week 48 the preference will be assessed between Oct-LAR intramuscular injections every four weeks and lanreotide Autogel 120 mg subcutaneous either

injected every four or every six or every eight weeks (as injected during phase

2 of the study treatment).

*AcroQoL will only be assessed in countries were a validated translation is

available (currently The Netherlands, Denmark, Sweden, France, Greece, Poland,

South Korea and Brazil).

Study description

Background summary

Acromegaly is the medical condition called when your body makes too much growth hormone (GH) from a non-cancerous (benign) tumour on the pituitary gland. The pituitary gland is a small gland located at the base of the brain behind the bridge of the nose. This gland produces many hormones. The tumour makes too much (GH) in the blood and this causes an increase in another hormone called Insulin-Like Growth Factor (IGF-1).
Somatostatin is a hormone naturally produced by the body that is responsible for reducing the GH in the blood. There are synthetic drugs (called somatostatin analogues) that have similar structure to natural somatostatin and have been used for many years to treat acromegaly. Two of these somatostatin analogues can be found in the market: lanreotide Autogel (Somatuline Autosolution) and octreotide LAR (Sandostatin LAR®). It is well known that these drugs reduce high GH levels in the blood and reduce the symptoms of acromegaly.

Study objective

The purpose of this study is to look at the effect of changing from monthly (4 weekly) injections of your usual treatment (octreotide LAR) to less frequent treatment (once every 6 or 8 weeks) with lanreotide Autogel 120 mg injections. The study doctor will monitor the treatment safety and the changes in your acromegaly symptoms during the whole study period. You will also be asked to give your opinion on which treatment schedule you prefer.

Study design

A prospective, international, multi-centric, open-label study, phase III / IV

Intervention

NA

Study burden and risks

Patients will not undergo more burden or risks under this protocol compared with thier normal standard care for the disease.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) The subject has given written informed consent prior to any study-related procedures.

2) The subject is male or female and is over 18 years of age.
3) The subject must have had documentation supporting the diagnosis of acromegaly.
4) The subject has been receiving octreotide LAR (10 or 20 mg) treatment for at least six months and is biochemically controlled. Control is defined as normal (age and sex adjusted) IGF 1 levels for two consecutive measurements (at least two months apart) preceding study entry.
5) If the subject is receiving dopamine agonist therapy, treatment should be stable for at least four months, and no change in their dopamine-agonist medication is expected during the entire study period.

Exclusion criteria

1) The subject has received radiation therapy to the pituitary gland before study entry.
2) The subject has a history of hypersensitivity to lanreotide or drugs with a similar chemical structure.
3) The subject has received a GH receptor antagonist (pegvisomant) therapy within three months before study entry.
4) The subject has undergone treatment with any other investigational drug in the 30 days before study entry or is scheduled to receive an investigational drug, other than lanreotide 120 mg, during the course of the study.
5) The subject has received any unlicensed drug within the 30 days prior to the baseline visit or is scheduled to receive an unlicensed drug during the course of the study.
6) The subject is anticipated to require pituitary surgery or to receive radiotherapy during the study.
7) The subject is likely to require treatment during the study with drugs that are not permitted by the study protocol (i.e., cyclosporine).
8) The subject is pregnant or lactating.
9) The subject is female and at risk of pregnancy during the study and is not using an acceptable contraceptive method. Females of childbearing potential must provide a negative pregnancy test at start of study and must be using oral, double barrier (condom with spermicidal jelly, foam suppository, or film; diaphragm with spermicide; or male condom and diaphragm with spermicide), injectable contraception or an intra uterine device. Non childbearing potential is defined as post-menopause for at least one year, surgical sterilisation or hysterectomy at least three months before the start of the study.
10) The subject has a history of, or known current, problems with alcohol or drug abuse.
11) The subject has any mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study, and/or evidence of an unco-operative attitude.
12) The subject has abnormal baseline findings: any medical condition(s) and/or known laboratory findings that, in the opinion of the investigator, might jeopardise the subject*s safety or decrease the chance of obtaining satisfactory data to achieve the objective(s) of the study.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2008
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Somatuline Autogel 120mg
Generic name:	Lanreotide (as acetaat)
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-06-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	24-09-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	19-11-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-02-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-03-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-01-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-01-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-06-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2007-005838-37-NL
ClinicalTrials.gov	NCT00701363
CCMO	NL22930.078.08