Anamorelin HCl in the Treatment of Non-Small Cell Lung Cancer - Cachexia (NSCLC-C): An Extension Study;(ROMANA-3)

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Based on the data available, Anamorelin HCl produces an increase in total body weight and Lean Body Mass in patients with advanced cancer, and specifically in patients with NSCLC, in addition to increasing muscle strength and improving quality of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON38190

Source
ToetsingOnline

Brief title
Helsinn HT-ANAM-303 extension study (ROMANA 3)

Condition

- Appetite and general nutritional disorders
- Miscellaneous and site unspecified neoplasms benign

Synonym
cachexie, wasting syndroom

Research involving
Human

Sponsors and support

Primary sponsor: Helsinn Therapeutics (U.S.), Inc
Source(s) of monetary or material Support: Helsinn Therapeutics

Intervention

Keyword: Anamorelin HCl, cachexia, non-small cell lung cancer

Outcome measures

Primary outcome

To evaluate the safety and tolerability of Anamorelin HCl.

Secondary outcome

To evaluate the effect of Anamorelin HCl on body weight

To evaluate the effect of Anamorelin HCl on muscle

strength as measured by handgrip strength (HGS)

To evaluate the effect of Anamorelin HCl on quality of life as assessed using

the FAACT (Functional Assessment of Anorexia/Cachexia Treatment) and the

FACIT-F (Functional Assessment of Chronic Illness Therapy - Fatigue)

To evaluate the effect of Anamorelin HCl on quality of life as assessed using

the

Hunger Assessment Scale

Study description

Background summary

Unexpected and rapid weight loss is universally recognized as a sign of disease. The importance of weight loss as both a symptom of cancer and contributor to morbidity and mortality from the disease has been recognized for many years. Up to 80% of terminally ill patients with cancer develop cachexia, which is often the direct cause of death. Despite the significant importance of

cancer cachexia, treatments are lacking. The drugs most commonly employed on an off-label basis are the appetite stimulants megestrol acetate and dronabinol, however, the majority of their induced weight gain is fat, not LEAN BODY MASS. Anamorelin HCl, by virtue of its ghrelin agonist activity and growth hormone (GH) releasing effects, serves a dual role in the reversal of cancer induced anorexia and cachexia. Anamorelin HCl is an orally active ghrelin mimetic and GH secretagogue. Growth hormone and GH secretagogues have a broad array of beneficial actions on various body systems, characterized by anabolic effects on Lean Body Mass and bone. The ghrelin mimetic, MK-7677, increases body weight and reverses the negative nitrogen balance induced by starvation in healthy volunteers; these effects are independent of its orexigenic effects. Acute administration of ghrelin to cancer patients exhibiting anorexia and weight loss increases appetite and food intake.
In Phase II clinical studies conducted by Helsinn Therapeutics, Anamorelin HCl was administered to patients with cancer-induced cachexia, and demonstrated an increase in Lean Body Mass, handgrip strength (HGS), and directional benefit in patient-reported outcomes. The non-peptidic small molecule Anamorelin HCl offers the promise of an orally available drug.
Weight loss with cachexia is a common presenting sign in NSCL-C. Overall the patients with weight loss had a significantly lower response rate, shorter progression free survival, and shorter overall survival than those not reporting weight loss.

Study objective

Based on the data available, Anamorelin HCl produces an increase in total body weight and Lean Body Mass in patients with advanced cancer, and specifically in patients with NSCLC, in addition to increasing muscle strength and improving quality of life measures. Therefore, the 100 mg daily dosing and study duration for 12 weeks was selected based on both the safety and efficacy data obtained in previous Anamorelin HCl clinical trials, and a low survival rate in NSCLC patients.
The primary purpose of this extension trial is permit patients to have the option to continue to receive randomized study drug for an additional 12 weeks. At the same time the effect of Anamorelin HCl will be measured on Body weight and on muscle strength as measured by Hand Grip Strength in patients with advanced NSCLC-C.

Study design

This study is an extension study of HT-ANAM-301 with Anamorelin HCl in NSCLC-C patients.
A Randomized, Double-Blind, Placebo-Group extension study to assess the Safety and Efficacy of Anamorelin HCl in Patients with NSCLC-C.

Patients who completed dosing in the original trial will have the option of

continuing in this separate double-blind extension study (HT-ANAM-303) in which patients will continue to be administered Anamorelin HCl 100 mg QD or placebo QD for an additional 12 weeks. The study will be approximately 17 weeks in duration including a screening period of up to 1 week, a 12-week treatment period and a 4-week follow-up period.

Patients are allowed to initiate a new chemotherapy and/or radiation therapy regimen during the 12-week treatment period.

Intervention

Investigational drug is Anamorelin HCl; 100 mg tablets; oral administration QD for 12 weeks, at least 1 hour before the first meal of the day. Subjects will have their blood drawn at 3 visits.

Study burden and risks

The study consists of a period of 17 weeks with 1) a screening period of up to 1 week, 2) a dubbel blind treatment period of 12 weeks and 3) a follow-up period of 4 weeks. There will be 6 visits in total. After this the patient will be tracked to register survival according their original protocol HT-ANAM-301. Blood will be drawn at 3 visits. There will be 1 physical examination and 2 ECGs. The Hand Grip Strenght will be measured 2 times.

Anamorelin HCl has been studied in approximately 156 healthy volunteers and in approximately 254 patients with cancer. Side effects that were reported frequently (in more than 10% of patients) with the use of the study drug are the following: swelling of the hands or feet, diarrhea, nausea, constipation, weakness, fever, and increased blood sugar. Infrequent side effects (occurring in fewer than 10% of patients) include: decreases in blood pressure following the first dose and increases in liver function tests. The studies conducted so far are not large enough to determine if there is an effect (either improvement or worsening) of Anamorelin HCl on either overall survival or tumor growth. As such the effect of the study drug on survival is not yet known.

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

• The patient has completed the Day 85 Visit in the original trial (Study HT ANAM-301 or HT-ANAM-302) and the Investigator considers the patient to be appropriate to continue to receive an additional 12 weeks of study drug administration. The patient must start dosing on the extension study within 5 days of completing dosing on the original trial.;• Females and males at least 18 years of age;• ECOG performance status less than / equal to 2

Exclusion criteria

• Women who are pregnant or breast-feeding;• Had major surgery (central venous access placement and tumor biopsies are not considered major surgery) within 4 weeks prior to enrollment into the extension study. Patients must be well recovered from acute effects of surgery prior to screening. Patients should not have plans to undergo major surgical procedures during the treatment period.;• Patients unable to readily swallow oral tablets. Patients with severe gastointestinal disease (including esophagitis, gastritis, malaborption, or obstructive symptoms) or intractable or frequent vomiting are excluded.;• Has known or symptomatic brain metastases

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2011
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Anamorelin HC1
Generic name:	nvt

Ethics review

Approved WMO

Date:	20-06-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	21-10-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-01-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	04-01-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	16-03-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	28-03-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	12-04-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	01-08-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	22-08-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	17-09-2012

Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	21-03-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	25-04-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	19-08-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	23-08-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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	EUCTR2010-023650-36-NL
CCMO	NL36817.068.11

Study results

Date completed: 15-10-2013

Actual enrolment: 1

Summary results
Trial is onging in other countries