Phase III multicentre, Randomised, Double Blind, Comparative study to assess the efficacy and safety of lanreotide 30mg versus placebo as a palliative treatment of clinical symptoms associated with intestinal obstruction due to peritoneal carcinomatosis in inoperable patients

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Primary objective:The primary objective of this study is to assess the efficacy of lanreotide 30 mg as compared to placebo to relieve clinical symptoms due to small bowel obstruction in inoperable patients with peritoneal carcinomatosis.Secondary...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON30314

Source
ToetsingOnline

Brief title
Lanreotide for ileus based on peritonitis carcinomatosa

Condition

- Gastrointestinal stenosis and obstruction
- Gastrointestinal neoplasms malignant and unspecified

Synonym
intestinal obstruction, peritoneal carcinomatosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: intestinal obstruction, Lanreotide, palliative treatment, peritoneal carcinomatosis

Outcome measures

Primary outcome

Primary efficacy criteria:

Pecentage of responder patients at D7.

A responder patient will be defined either as a patient experiencing one or

less vomiting episode per day during at least three consecutive days or as a

patient in whom NGT has been removed during at least three consecutive days

without vomiting recurrence.

Secondary outcome

Secondary criteria:

Efficacy criteria

- Number of daily vomiting episodes recorded in the diary cards or measurement

of the daily drainage by NGT

- Number of days with no vomiting episodes

- Number of daily nausea episodes recorded on diary cards

- intensity of abdominal pain assessed on a visual analogue scale

- Well-being assessed on a visual analogue scale

- Time between first injection (inclusion) and clinical response

- Symptom relief duration

- Symtomatic concomitant treatment consumption

- Hospitalisation duration

Safety criteria

- Clinical and biological adverse events

Study description

Background summary

Previous studies have shown that vomiting and pain due to bowel obstruction could be controlled by somatostatin analogues administered daily by subcutaneous injections in patients unresponsive to conventional therapy. Considering that a prolonged release of somatostatin analogues is as effective and more convenient for clinical use than discontinued injections, it has been decided to evaluate, by a placebo - controlled, randomised study, the efficacy of one intra-muscular injection of lanreotide 30 mg in the managment of symptoms secondary to inoperable intestinal obstruction in terminal cancer patients.

Study objective

Primary objective:
The primary objective of this study is to assess the efficacy of lanreotide 30 mg as compared to placebo to relieve clinical symptoms due to small bowel obstruction in inoperable patients with peritoneal carcinomatosis.

Secondary objectives:
To assess the efficacy of lanreotide 30mg as compared to placebo in terms of:
- vomiting improvement or decrease in the secretion volume sucked up by a nasogastric tube
- nausea improvement
- pain improvement
- well-being improvement
- symptom improvement delay
- symptom improvement duration

- concomitant medications consumption
- hospitalisation duration
To assess the clinical and biological safety of treatment.

Study design

- Blinded phase: this phase will be a randomised, double-blind, comparative, placebo controlled phase carried out on 2 parallel groups

- Open phase: this phase will be a non randomised one. According to investigator's and patient's decision at the end of the blinded phase, patients will receive (or not) injections of open-labelled lanreotide every 10 days. Patients will be eligible to enter the open phase only upon completion of the blinded phase.

Intervention

Not applicable

Study burden and risks

The risk associated with participation in the study are those associated with the administration of lanreotide 30mg. None of the procedures being performed during this study are additional to the treatment that would otherwise be employed.

The drug risks are digestive disorders (diarrhoea, constipation, abdominal pain) and transient pain at the administration site.
Considering that lanreotide 30mg may modify insulin and glucagon secretion, changes in glycaemic balance could occur.

Due to antisecretory properties, lanreotide 30mg is expected to relief clinical symptoms (e.g. vomiting, nausea, pain) associated to bowel obstruction and thus also to shorten the hospitalisation duration.

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

- Patient having given written (personally signed and dated) informed consent before completing any study related procedure,
- Patient being over 18 years of age
- Patient having a high digestive obstruction i.e. located on the upper part of the gastro-intestinal tract (stomach, duodenum, small bowel)
- Patient having a digestive obstruction of malignant origin.
- Patient having a peritoneal carcinomatosis confirmed by a CT Scan within the previous 3 months
- Patient having an obstruction with at least two vomiting episodes per day or the presence of a nasogastric suction tube
- Patient for whom surgery is inappropriate, either documented in the medical records or confirmed by a surgical advice within the previous 72 hours
- Patients being treated by intra-venous corticoids since at least 5 days and intravenous proton pump inhibitors
- Patients having an estimated survival of more than one month
- Patients accepting to comply fully with the protocol.

Exclusion criteria

- Patient having an operable obstruction
- Patient having a colic obstruction (must be documented by an abdominal X-Ray within the

previous 3 days)
- Patient having received any specific anticancer therapy within the previous 15 days
- Patient receiving any antiH2 receptor blockers
- Patient having a bowel obstruction which could be explained by a non malignant cause (e.g. hypokaliaemia, drug side-effects, renal insufficiency)
- Patient having signs of bowel perforation
- Patient having received somatostatin or any analogue as treatment of the bowel obstruction
- Patient having a contraindication to intra-muscular injections
- Patient having a known hypersensitivity to any of the test materials or related compounds
- Patient having previously entered this study
- Patient having been included in another clinical study within the previous 30 days.

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:	Pending
Start date (anticipated):	15-01-2007
Enrollment:	6
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Somatulin PR
Generic name:	lanreotide acetat
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	29-12-2006
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	EUCTR2005-002349-38-NL
CCMO	NL15623.018.06