A randomized clinical trial investigating LanreotIde For output reduction in patients with high-output Enterocutaneous fistula or enterostomie

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To assess the impact of treatment with Lanreotide versus current standard of treatment on output reduction in patients with high output enterocutaneous fistula or high-output stoma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON44776

Source
ToetsingOnline

Brief title
LIFE study

Condition

- Gastrointestinal therapeutic procedures

Synonym
connection between gasrointesinal tract and the skin whereby losing many fluids and electrolytes, high out-put enterocutaneous fistula or high-output enterostomie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: investigator initiated op basis van diverse externe bronnen

Intervention

Keyword: high-output enterocutaneous fistula, high-output enterostomie, Lanreotide, output reduction

Outcome measures

Primary outcome

The primary endpoint is the number of responders in week 8. Definition of a

responder is a decrease in output of >25% at week 8 compared with baseline

output. Output will be assessed for 8 weeks or until surgery if within 8 weeks;

in mL/24 hrs.

Secondary outcome

Secondary endpoints are days to full oral or enteral nutrition, change in need

of intravenous fluid/TPN per week, time to reach the maximal effect in fistula

output, percent reduction in total fistula or stoma output from pre

randomisation, total number of days in hospital, changes in needed

electrolytes (calcium, magnesium, potassium, phosphate, bicarbonate), wound

care, quality of life (EQ-5D/qaly*s), analysis of costs, absolute fistula or

stoma output volume at endpoint compared with output volume at randomisation.

Study description

Background summary

High output fistulas or high-output enterostomies are associated with a number of complications such as dehydration, malnutrition, psychological and wound care problems due to the nature of the condition. Lanreotide inhibits the exocrine secretion of gastrointestinal fluid and increases the net absorption

of water and electrolytes. Because of these properties, Lanreotide is believed to be useful in output reduction in high-output fistulas or high-output enterostomies. Reduction of fistula or stoma output by 25% could prevent artificial nutritional support, dehydration and wound care problems and improve the quality of life. Lowering output could lead to a reduction of admission time or number of readmissions, and thereby reduce hospital stay and costs of treatment.

Study objective

To assess the impact of treatment with Lanreotide versus current standard of treatment on output reduction in patients with high output enterocutaneous fistula or high-output stoma.

Study design

This is a randomized, non blinded multicenter clinical trial comparing standard of care with standard of care combined with Lanreotide for adult patients with a high output small bowel fistula (> 500ml/day) or high-output enterostomie (>1500ml/day) after gastro-intestinal or abdominal wall surgery. The primary objective is to compare the proportion of responders to treatment (a responder is defined as decrease in output > 25% in week 8 compared with baseline output).

Intervention

Patients will be randomized to one of the following two treatment strategies: standard treatment for high output fistula or high-output enterostomy according to our local protocol or standard treatment combined with Lanreotide autosolution 120 mg deep subcutaneously, once every four weeks.

Study burden and risks

Both treatment regimens are currently used as standard of care in the Netherlands and the investigational product is used off label for the treatment of high output enterocutaneous fistula or high-output enterostomies. Possible benefits of Lanreotide are lower risk of recurrent readmissions, less wound problems or less dehydration/malnutrition related to high output. Lowering output could lead to a reduction of admission time or number of readmissions, and thereby reduce hospital stay. The most commonly expected adverse drug reactions following treatment with Lanreotide 120 mg are gastrointestinal disorders (most commonly reported are diarrhoea and abdominal pain, usually mild or moderate and transient), cholelithiasis (often asymptomatic) and injection site reactions (pain, nodules and indurations).

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

All adult patients with a high-output fistula (> 500ml/day) or high-output enterostomie (<1500 ml/day) after gastro-intestinal, abdominal wall surgery will be registered from the moment are referred to our multi-disciplinary outpatient treatment team. ;Inclusion criteria for randomization:
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* Adult patients minimal 4 weeks after abdominal surgery
* Received minimal 2 weeks standard treatment
* High output small bowel fistula (>500ml/day) or enterostomy (>1500ml/day) for at least 3 consecutive days.
* The diagnosis of fistula origin and localization confirmed by CT/fistulography/ enteral contrast MRI.

Exclusion criteria

Exclusion criteria
A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Treatment with short-acting somatostatin (or analogues) in the last 2 weeks or with a long-acting somatostatine analogue in the last 2 months.
* Patients with high output pancreatic fistula after pancreatitis
* Patients with symptomatic gallbladder disease

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2014
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Somatuline AutoSolution 120 mg
Generic name:	Lanreotide (INN) acetate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-10-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-12-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-04-2016

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-04-2017
Application type:	Amendment
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	EUCTR2013-003998-10-NL
CCMO	NL46334.018.13