Treatment of dumping syndrome with Lanreotide Autogel

Published: 10-04-2007
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To determine the efficacy and tolerability of L-Autogel in patients with early or late dumping syndrome after gastric surgery.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal signs and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON31107

Source
ToetsingOnline

Brief title
TDLA

Condition

- Gastrointestinal signs and symptoms

Synonym
Dumping syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dumping syndrome, Lanreotide Autogel, Treatment

Outcome measures

Primary outcome

Responses on the dumping provocation tests

Secondary outcome

-Dumping symptoms, side effects and tolerability as measured by a treatment specific questionnaire (TSQ)

-The global severity of symptoms is measured by a Global Disease Severity Score (GDSS)

-The severity of other abdominal symptoms including upper abdominal pain, lower abdominal pain, nausea/vomiting, fullness/satiety, bloating, upper abdominal pain, heartburn/regurgitation, lower abdominal pain, diarrhoea, constipation.

-Health related quality of life (HRQL)

-Global relief score (GR)

-Global evaluation of efficacy score (GEES)

-Concomittant pain medication

-Faecal fat excretion

-Body weight

-Gallbladder ultrasound

Study description

Background summary

The dumping sydrome is a serious complication in 10-20% of patients after gastric surgery. These symptoms occur during, immediately or 1 or 3 hours after meal ingestion and consists of both gastrointestinal and cardiovascular components.

Somatostatine analogues are effective in controllling early and late dumping symptoms. Lanreotide is a new somatostatin analogue and is well tolerated with fewer local side effects and technical problems with injection when compared to octreotide LAR.

Study objective

To determine the efficacy and tolerability of L-Autogel in patients with early or late dumping syndrome after gastric surgery.

Study design

Prospective open label switch study

Study burden and risks

Patients will be asked to discontinue the Sandostatine they used for dumping symptoms for six weeks. Thereafter they can develop dumping symptoms, to protect for symptoms patients are allowed to use short acting octreotide 3 days before V2.

L-Autogel is tolerated with fewer local side effects and technical problems with injections

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

Dumping provocation test positive
Dumping symptoms devised by Sigstad
Patients with late dumping are selected by postprandial hypoglycaemie plasma glucose <3.0 after 60 min after ingestion of 50 g glucose/m2 body surface and hypoglycaemic symptoms at least 60 min after the oral glucose load.
Patients who have long term octreotide LAR therapy
Age 18 years or older
Informed consent

Exclusion criteria

Patients with disorders of endocrine system
Patients with severe kidney , liver, cardiovascular disease.
Patients who are pregnant or giving breast feeding
Patinets with recent gastrointestinal surgery or other gastrointestinal diseases

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2007
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Somatuline
Generic name:	Lanreotide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	10-04-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2007-001078-94-NL

Register	ID
CCMO	NL16803.091.07