A clinical trial investigating the effect of Lanreotide on the reduction of output in patients with high-ouput enterocutaneous fistula or high-output enterostomy

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High-output enterocutaneous fistula (>500ml/day) or high-output enterostomy (>1500 ml/day) are associated with a number of complications such as dehydration, malnutrition psychological and wound care problems. Lanreotide inhibits the exocrine...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25162

Bron
Nationaal Trial Register

Verkorte titel
LIFE study

Aandoening

enterocutaneous fistula, enterocutane fistels, Lanreotide, output reduction, output reductie

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: investigator initiated

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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 at randomisation.

Toelichting onderzoek

Achtergrond van het onderzoek

In this randomized clinical trial we assess the influence of Lanreotide on the reduction of output in patients with high output enterocutaneous fistula or high-output enterostomy.

Doel van het onderzoek

High-output enterocutaneous fistula (>500ml/day) or high-output enterostomy (>1500 ml/day) are associated with a number of complications such as dehydration, malnutrition psychological and wound care problems. 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. This study aims to assess the impact of treatment with Lanreotide on fistula or stoma output.

Onderzoeksopzet

Follow up at 5,8,9,13,16 weeks

Onderzoeksproduct en/of interventie

Standard care + Lanreotide 120mg deep subcutaneous injections once every 4 weeks versus standard of care

Contactpersonen

Publiek

AMC, Amsterdam
S.L. Gans
Amsterdam

The Netherlands
-

Wetenschappelijk

AMC, Amsterdam
S.L. Gans
Amsterdam
The Netherlands
-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- aged 18 years or older

- confirmed diagnosis and localisation of fistula origin (CT/fistulography/enteral contrast MRI)

- Clinical decision by treatment team to start medical and nutritional therapy to reduce output
- high output fistula (>500ml/day) or high-output enterostomy (>1500ml/day) during 3 consecutive days

- at least 4 weeks post-operative after abdominal surgery and received at least 2 weeks ‘standard care’

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- recent treatment with short acting somatostatin analogues (>1 week consecutive treatment in past 3 months)

- High ouput fistula after pancreatitis or pancreatic surgery

- symptomatic gallbladder disease

- pregnancy or breastfeeding

- known hypersensitivity for Lanreotide, Somatostatin analogues or one of the compounds of the drugs

- Patients in whom concomitant administration of Lanreotide and Cyclosporine cannot be avoided
-Patients in whom concomitant administration of Lanreotide and Bromocriptine cannot be avoided
- Patients taking drugs with a narrow therapeutic window that are mainly metabolized by CYP3A4.

- Pancreas fistula

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2014
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-02-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4293
NTR-old	NTR4437
Ander register	NL46334.018.13 : 2013-003998-10

Resultaten