

The effect of lanreotide on non-functioning pituitary macroadenoma size

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Lanreotide therapy can stabilize or reduce tumor size in Gallium-68 DOTATATE positive pituitary NFMA

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

Samenvatting

ID

NL-OMON27861

Bron

NTR

Verkorte titel

GALANT

Aandoening

pituitary adenoma
hypofyse adenoom

Ondersteuning

Primaire sponsor: Prof. dr. E. Fliers, Academic Medical Center, University of Amsterdam

Overige ondersteuning: Ipsen Farmaceutica BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in cranio-caudal NFMA size

Toelichting onderzoek

Achtergrond van het onderzoek

In patients with clinically non-functioning pituitary macroadenomas (NFMA), the current therapeutic approach is to substitute any hormonal deficits, and to perform transsphenoidal surgery if necessary. However, the remission rate after surgery is only 44% due to extensive growth on diagnosis. The available evidence concerning treatment and follow-up of NFMA is based exclusively on small, observational studies with a lack of well-designed randomized trials. It has been known for some decades that NFMA may express somatostatin receptors, as seen in surgical specimens and in vivo, using Indium-111 pentetreotide SPECT. We hypothesize that positive somatostatin receptor imaging with Gallium-68 DOTATATE PET/CT in pituitary NFMA predicts response to somatostatin analogue therapy and that this therapy will reduce the growth rate and/or tumor size in NFMA patients. We will therefore randomize 44 patients with positive NFMA uptake on Gallium-68 DOTATATE PET/CT to either lanreotide or placebo. Based on an expected PET-positivity rate of 66%, we expect to need to include a maximum of 66 patients to be able to randomize 44 patients.

Doel van het onderzoek

Lanreotide therapy can stabilize or reduce tumor size in Gallium-68 DOTATATE positive pituitary NFMA

Onderzoeksopzet

baseline, 6 months, 12 months and 18 months

AE's will be registered continuously

Onderzoeksproduct en/of interventie

Gallium-68 DOTATATE PET/CT

> positive PET/CT: randomization:

Group 1 monthly subcutaneous injections of somatostatin analog (18 months)

Group 2 monthly subcutaneous injections of placebo (18 months)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult patients (>18 yrs)

Clinically non-functioning pituitary macroadenoma with suprasellar extension

[Positive PET/CT scan > this is a study procedure, performed after patient inclusion]

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Optic chiasm compression with visual field defects

Hypersensitivity for somatostatin or similar peptides

Obstructive neuroendocrine gut tumor

Previous radiation therapy in the pituitary region

Known symptomatic cholelithiasis

Use of dopamine agonists or somatostatin analogues in the past 6 months

Pregnancy (plans)

Any contraindication to perform MRI with gadolinium based contrast agent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	03-11-2015
Aantal proefpersonen:	44
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	14-07-2015
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	NL5136
NTR-old	NTR5275
Ander register	METC AMC : METC 2015_103 (ABR NL52821.018.15)

Resultaten

Samenvatting resultaten

<https://bmjopen.bmj.com/content/10/8/e038250>