Kortetermijneffect van een eucalorisch ketogeen dieet op de ziekte acromegalie

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Several studies have shown in health subjects that when restricted carbohydrates are ingested, the decrease in portal vein insulin concentration can lead to a reduction in IGF-I synthesis by the liver. However, in pathophysiological states,...

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

Samenvatting

ID

NL-OMON27621

Bron
NTR

Aandoening

- Patients with active acromegaly (IGF-I levels above 120% ULN)
- Ziekte acromegalie

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess the efficacy of two weeks eucaloric ketogenic diet on GH and IGF-I levels in acromegaly patients. The primary endpoints are the difference in GH and IGF-I levels before and after 2 weeks of ketogenic diet.

Toelichting onderzoek

Achtergrond van het onderzoek

This will be a single-centre, prospective, proof-of-concept intervention study to assess the efficacy of two weeks eucaloric ketogenic diet on GH and IGF-I levels in acromegaly patients.

Doel van het onderzoek

Several studies have shown in health subjects that when restricted carbohydrates are ingested, the decrease in portal vein insulin concentration can lead to a reduction in IGF-I synthesis by the liver. However, in pathophysiological states, including increased insulin resistance which is a frequent consequence of acromegaly, the hybrid receptor number is changed significantly, thus potentially abrogating the chance for IGF-I to alter glucose metabolism. To our knowledge, the effect of eucaloric ketogenic diet on GH and IGF-I secretion, including the effect of insulin on IGF-I levels, in acromegaly patients has not been studied yet.

Onderzoeksopzet

Blood biochemistry: (t0 =baseline, t1= week 1 and t2= week 2) • IGF-1 levels • GH levels • IGF-BP1 levels • Fasting plasma glucose, insulin, HbA1c levels, HOMA-IR • Total cholesterol, HDL-cholesterol and LDL-cholesterol levels • Triglycerides, free fatty acids • AST, ALT, alkaline phosphatase, gamma-glutamyltransferase, lactate dehydrogenase (LDH) Note: all the following laboratory evaluations will be performed at the study site. Urine: (t1= week 1 and t2= week 2) One voided sample of urine will be collected at the study site. One dipstick strip is used to measure ketones. This test is used for monitoring the compliance during a ketogenic diet. Vital signs: (t0 =baseline, t1= week 1 and t2= week 2) Pulse rate and blood pressure were measured after 5 minutes of rest in the seated position at the outpatient clinic. Anthropometric measurements: (t0 =baseline, t1= week 1 and t2= week 2) Height and body weight were obtained at the outpatient clinic; patients will be weighted clothed without shoes. Body composition will be assessed at the outpatient.clinic by Body Impedance Assessment. Waist-to-hip ratio were measured as follows. The waist was defined as the minimal abdominal circumference located midway between the lower rib margin and the iliac crest. The hip was defined as the wides circumference over the great trochanters.

Circumferences were measured with the subjects in the standing position using flexible tape measure and maintaining close contact with the skin without compression of underlying tissues. Questionnaire: (t1= week 1 and t2= week 2) One questionnaire will be filled out at the outpatient clinic(¡§Vragenlijst gebruik en effecten dieetproduct¡¨) Food diary: (t0 =baseline, t1= week 1 and t2= week 2) Three-day food records during baseline and after each week of diet will be filled out at the outpatient clinic (¡§3 dagen voedingsdagboek¡¨). Subject are instructed by the dietician how to fill it out.

Onderzoeksproduct en/of interventie

All ten subjects will receive a ketogenic diet for two weeks

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria : Male or female subject of 18 years or older; „h Documentation supporting the diagnosis of acromegaly based on elevated GH and/or IGF-I levels due to a pituitary tumor; Subjects must be willing and able to comply with study restrictions and to remain at the clinic for the required duration during the study period and willing to return to the clinic for the follow-up evaluation as specified in the protocol; Signed informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study: „h Has undergone pituitary surgery or radiotherapy within 6 months prior to study entry; „h It is anticipated that the patient will receive pituitary surgery or radiotherapy during the study; „h History or presence of epilepsy; „h Participation in a trail of an experimental drug or device within 30 days prior to screening; „h Has a mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study, and/or evidence of an uncooperative attitude; „h Has abnormal baseline findings, any other medical condition(s) or laboratory findings that, in the opinion of the investigator, might jeopardize the subjects safety or decrease the chance of obtaining satisfactory data needed to achieve the objective(s) of the study; „h Diabetes type 1 or diabetes type 2 and using insulin „h Use of systemic corticosteroids within 60 days prior to screening Females of childbearing potential must be using contraception (we do not perform a pregnancy test), otherwise excluded from the study

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-06-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46800
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7093
NTR-old	NTR7291
CCMO	NL64773.078.18
OMON	NL-OMON46800

Resultaten