Kortetermijneffect van een eucalorisch ketogeen dieet op de ziekte acromegalie

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27621

Source
NTR

Health condition

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

Sponsors and support

Primary sponsor: J.L.C.M. van Saase, MD, PhD
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Source(s) of monetary or material Support: J.L.C.M. van Saase, MD, PhD
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Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary objective of the study is to evaluate safety and the effect of a eucaloric ketogenic diet on: „h blood glucose levels; „h insulin secretion; „h body weight; „h lipid profile, especially on triglycerides and free fatty acids

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

All ten subjects will receive a ketogenic diet for two weeks

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion
Date: 19-06-2018
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46800
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results