

Ghrelin levels in patients with ACNES (Anterior Cutaneous Nerve Entrapment Syndrome) and gastrointestinal complaints, loss of appetite and weight loss.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25017

Source

NTR

Brief title

Ghrelin-ACNES

Health condition

ACNES (Anterior Cutaneous Nerve Entrapment Syndrome)

Sponsors and support

Primary sponsor: Not applicable.

Source(s) of monetary or material Support: Stichting SolviMáx Research

Intervention

Outcome measures

Primary outcome

The main study parameter is the difference in fasting ghrelin blood level between ACNES patients and a healthy control group.

Secondary outcome

The secondary study parameters are:

- The difference in fasting ghrelin blood level before and after treatment for ACNES.
- The difference in fasting ghrelin blood level after treatment for ACNES between the ACNES patients with a successful therapy and those with a failed therapy.

Study description

Background summary

Rationale: The abdominal wall is an under recognized cause of abdominal pain, often due to the anterior cutaneous nerve entrapment syndrome (ACNES) (1-3). This is caused by unknown triggering of the anterior and lateral cutaneous branches of anterior rami of thoracic intercostal nerves 7th-12th penetrating the rectus abdominis muscle. These nerves innervate the abdominal wall sensory (4). Our centre has noticed that about half of the ACNES patients exhibit a range of so called pseudovisceral complaints such as bloating, relation of pain to food ingestion, nausea, weight loss, etc. (5). We hypothesize that these symptoms may reflect a disturbed segmental relation between a viscus and a dermatoma resulting in a Head zone (6). Following this line of thought, the effect of percutaneous electrical neurostimulation of these nerves was recently evaluated in a RCT in obese patients. It was concluded that stimulation of Th 6 nerves resulted in a significant loss of appetite and weight loss that was most probably due to the creation of a somato-autonomic reflex (7). The same research group described a direct correlation between appetite reduction and ghrelin reduction after treatment with electrical neurostimulation at Th 6 nerve level in obese patients (10). Ghrelin is a peptide hormone produced by mainly the gastric fundus that induces appetite. The aim of this study is to demonstrate that there is an association between ACNES and pseudovisceral complaints, We hypothesize that in patients with ACNES and visceral complaints with a loss of appetite and weight loss, ghrelin levels are lowered. The results of this study could learn us more of the etiology of ACNES.

Objective: The aim of this study is to verify our theory of an association between ACNES and pseudovisceral symptoms. We hypothesize in this study that fasting ghrelin blood level in ACNES patients with pseudovisceral symptoms and weight loss is lowered in comparison with a healthy control group.

Study design: Matched pilot study with 40 participants (intervention group n= 20, control group n=20).

Study population:

- Intervention group: ACNES patients with visceral complaints and weight loss, age 18-65, BMI <30.

- Control group: healthy volunteers without ACNES, age 18-65, BMI <30.

Intervention:

- Intervention group: at baseline and 6 weeks after last treatment a fasting venepuncture and questionnaire. During treatment optional questionnaires.
- Control group: at baseline questionnaire for selection and after selection a fasting venepuncture.

Main study parameters/endpoints:

- The difference in fasting ghrelin blood level between ACNES patients and a healthy control group.
- The difference in fasting ghrelin blood level before and after treatment for ACNES.
- The difference in fasting ghrelin blood level after treatment for ACNES between the ACNES patients with a successful therapy and those with a failed therapy.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients do not benefit of participation in this study but the outcome of this study can contribute to the knowledge of ACNES. Patients receive investigation and treatment as by standard of care for ACNES. There are no major risks involving fasting venepuncture. Timing will be in consultation with the patient (day of surgery, with consultation in the morning, etc.).

Study objective

The aim of the primary objective is to verify our theory (`proof of concept`) of an association between ACNES and pseudovisceral symptoms. This will give us more insight in the etiology of ACNES. Our theory is that these pseudovisceral symptoms may be a reflection of a compromised or disturbed segmental relation between the viscus and the thoracic nerve resulting in a painful head zone. We hypothesize in this study that fasting ghrelin blood level in ACNES patients with pseudovisceral symptoms and weight loss is lowered in comparison with a healthy control group.

Secondary objective is to investigate a change in ghrelin blood levels in ACNES patients before and after their treatment. Our theory is that after successful treatment patients do not experience the visceral complaints anymore. Thereby, we hypothesize that ghrelin blood level is changed to more normal levels. We are also interested in a possible association between treatment outcome (success versus failure) and ghrelin blood levels. In this case, we hypothesize that ghrelin blood level is not changed after a failed treatment.

Study design

Baseline (week 0) : start of the study before treatment

- Use of data in the EPD
- Additional questionnaire (see F1a)
- One fasting blood sample by venepuncture at our hospital

During treatment (optional)

- Use of data in the EPD
- Additional questionnaire in follow-up (see F1a) for changes in weight, medication and

medical conditions if patient is visiting our outpatient department

6 weeks after finishing treatment (week 6 - month 6): study end

- Use of data in the EPD
- Additional questionnaire (see F1a)
- One fasting blood sample by venepuncture at our hospital

Intervention

Questionnaire and 2 samples of fasting blood by venepuncture.

Contacts

Public

Maxima Medisch Centrum
Monica Jacobs

0032476501837

Scientific

Maxima Medisch Centrum
Monica Jacobs

0032476501837

Eligibility criteria

Inclusion criteria

Intervention group:

- diagnosed with ACNES
- at least two pseudovisceral complaints including loss of appetite related to pain and weight loss defined as: unintentional and more than 5% of usual body weight over at least 6 months
- age between 18 and 65
- receiving treatment for ACNES at our hospital
- obtained written informed consent

Control group:

- age between 18 and 65
- obtained written informed consent

Exclusion criteria

Intervention group:

- BMI \geq 30 kg/m²
- recent intra-abdominal pathology
- history of bariatric surgery
- endocrine disease
- psychiatric disorder
- can't obtain adequate follow-up
- pregnancy
- language barrier

Control group:

- BMI \geq 30 kg/m²
- ACNES
- weight loss over the last 6 months
- visceral complaints over the last month
- intra-abdominal pathology or surgery
- endocrine disease
- psychiatric disorder
- pregnancy
- language barrier

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2020
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date: 16-07-2020

Application type: First submission

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
NTR-new	NL8779
Other	METC Maxima Medisch Centrum : W20.066

Study results