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

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Abdominal hernias and other abdominal wall conditions
Study type	Observational invasive

Summary

ID

NL-OMON52437

Source
ToetsingOnline

Brief title
Ghrelin level in ACNES

Condition

- Abdominal hernias and other abdominal wall conditions

Synonym
abdominal wall nerve entrapment syndrome, Chronic Abdominal Wall Pain (CAWP)

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Onderzoeksfonds: Stichting SolviMáx Research

Intervention

Keyword: ACNES, Ghrelin, Weight loss

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 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

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.

Study 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 (20 intervention groep and 20 control group)

Study burden and risks

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 risk involving venepuncture for two times one blood sample. Timing will be in consultation with the patient (day of surgery, whith consultation in the morning, etc.).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

For the ACNES 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

For the control group
- age between 18 and 65
- obtained written informed consent

Exclusion criteria

For the ACNES group
- BMI >= 30 kg/m2
- recent intra-abdominal pathology
- history of bariatric surgery
- endocrine disease
- psychiatric disorder
- can*t obtain adequate follow-up
- pregnancy
- language barrier

For the control group
- BMI >= 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 invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-11-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	25-08-2020
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO

Date:	14-12-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL72860.015.20
Other	pending nederlands trial register