The effect of lidocaine infusion on ad libitum food intake and satiety in healthy volunteers

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON53382

Source
ToetsingOnline

Brief title
Lidocaine infusion and food intake

Condition

- Appetite and general nutritional disorders

Synonym
food intake

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: food intake, Lidocaine, satiety

Outcome measures

Primary outcome

To investigate the effect of intragastric infusion of lidocaine on ad libitum

food intake

Secondary outcome

To investigate the effect of intragastric infusion of lidocaine on

satiety/satiation.

To study the effect of intragastric infusion of lidocaine on gastrointestinal

complaints.

Study description

Background summary

World*s population over 60 years old is increasing rapidly. It is expected that in 2050 elderly population will be 22% of the total population, representing around 2 billion people. This situation means a rising in the incidence of elderly-related diseases, and thereby the need for long-term care. Reduction in body fat and weight are a common problem among the institutionalized elderly. Some factors that contribute to the anorexia of aging are decreased perception of hunger and increased satiation. This represents an increased risk of developing cachexia even during minor illnesses. The potentially severe consequences of anorexia of aging a greater understanding of the underlying mechanism of these changes is highly important.

Intraesophageal and intragastric infusion of 20mg/kg lidocaine results in an increase in food intake in Wistar rats (13). All infusions were done 30 minutes before the start of the meal intake (meal consisted of mealworms). Except for esophagus, in this setting the infusion was performed 15 minutes before the start of the meal intake.

It may be possible to decrease satiation, increase hunger, and hence food

intake in elderly individuals through gastric infusion of the anesthetics lidocaine or benzocaine. In the future this study could potentially contribute to improve food intake in elderly vulnerable of losing bodyweight.

Therefore, the current study aims to investigate the effect of intragastric administration of lidocaine on food intake, satiety/satiation and gastrointestinal complaints.

Study objective

We hypothesize that intragastric infusion of lidocaine will result in a delay of postprandial satiation and hereby an increase in food intake at an ad libitum meal. Furthermore, we hypothesize that lidocaine infusion will not result in an increase in any gastrointestinal complaints.

Study design

Double blind randomized placebo-controlled cross-over trial

Intervention

Lidocaine infusion into the stomach

Study burden and risks

Visual Analogue Scales (VAS) scores for satiety feelings (e.g., satiety, fullness, hunger, prospective feeding, desire to eat, desire to snack) and gastrointestinal symptoms (burning, bloating, belching, cramps, colics, warm sensation, sensation of abdominal fullness, nausea and pain) will be measured using VAS (0 to 100 mm) anchored at the low end with the most negative or lowest intensity feelings (e.g., extremely unpleasant, not at all), and with opposing terms at the high end (e.g., extremely pleasant, very high, extreme). Volunteers will be asked to indicate on a line which place on the scale best reflects their feeling at that moment. The scoring forms will be collected immediately so that they cannot be used as a reference for later scorings. Catheter placement: the subjects will perceive mild discomfort during the placement of the catheter. Subjects can, at any time, come in contact with the investigator if any problems occur. All participants are healthy volunteers and we don't expect any health benefits or disadvantages.

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Based on medical history and previous examination, no gastrointestinal complaints can be defined.
* Age between 18 and 50 years. Several studies (see introduction) showed a difference in response to a meal between young and elderly people. Inclusion of elderly could interfere with the outcome of this study. Goal of this study is to investigate whether a difference in food intake can be found after intragastric infusion of a local anaesthetic. For this proof of concept study we therefore choose to include healthy male volunteers with a maximum age of 50 years. This study will include healthy male subjects.
* BMI between 20 and 25 kg/m2)
* Weight stable over at least the last 6 months (*5% weight change)

Exclusion criteria

* Females, because of their hormonal cycle and the possible influence of these hormones on eating behaviour.
* History of severe cardiovascular, respiratory, urogenital, gastrointestinal/hepatic, haematological/immunologic, HEENT (head, ears, eyes, nose, throat), dermatological/connective tissue, musculoskeletal, metabolic/nutritional, endocrine, neurological/psychiatric diseases, allergy, major surgery and/or laboratory assessments which might limit participation in or completion of the study protocol. The severity of the disease (major interference with the execution of the experiment or potential influence on the study outcomes) will be decided by the principal investigator.
* Use of amiodaron, because of the cardiotoxicity (in combination with lidocaine).
* Use of beta blockers, cimetidine and norepinephrine (synergetic effect on the action of Lidocaine).

* Other use of medication, which could interfere with the outcome of the study. This will be decided by the principal investigator.
* Administration of investigational drugs or participation in any scientific intervention study which may interfere with this study (to be decided by the principle investigator), in the 90 days prior to the study
* Major abdominal surgery interfering with gastrointestinal function (uncomplicated appendectomy, cholecystectomy and hysterectomy allowed, and other surgery upon judgement of the principle investigator)
* Dieting (medically prescribed, vegetarian, diabetic, macrobiological, biological dynamic)
* Excessive alcohol consumption (>20 alcoholic consumptions per week)
* Smoking
* Self-admitted HIV-positive state
* Any food allergy
* Not able to eat a chili con carne meal.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2017
Enrollment:	35
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lidocain
Generic name:	Lidocaine Hydrochloride

Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	29-03-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	2016-001900-47
CCMO	NL57719.068.16