Peripheral and Central Nervous System Contributions to the Subjective Experience of Emotions

Published: 18-01-2021
Last updated: 08-04-2024

The primary objective of this study is to identify the distinct roles of the peripheral and central nervous system in the subjective experience of panic.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON49383

Source
ToetsingOnline

Brief title
PNS vs. CNS in Experimental Panic

Condition

- Anxiety disorders and symptoms

Synonym
anxiety attacks, Panic attack

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brain, Emotions, Panic, Periphery

Outcome measures

Primary outcome

Main study parameters are changes (from pre- to immediately post- CO_2 inhalation) per condition (atenolol, metoprolol, placebo) in fear, discomfort and panic symptom ratings, as measured by questionnaires.

Secondary outcome

Secondary outcomes are changes in physiological parameters (e.g., skin conductance, heart rate).

Study description

Background summary

Panic attacks (PA) are unexpected periods of intense fear concomitant with both strong physiological arousal and subjective symptoms. It is unclear whether this physiological arousal is necessary for the subjective experience of PAs, or whether these symptoms are an epiphenomenon of central processes. The (nor)adrenergic system is involved in emotion-related processes in the brain and in the peripheral nervous system (e.g. in the increase in heart rate, which is related to arousing emotions). PAs are most commonly associated with panic disorder (PD), but can occur in any mental disorder. These unexpected, recurrent attacks severely impact patients* quality of life and lead to immense health care costs to society.
Beta blockers are drugs that inhibit the activation of the (nor)adrenergic system. Beta blockers either selectively block beta receptors in the periphery, or both in the central and peripheral nervous system. This distinction in beta blockers can be used to study a fundamental, yet unanswered, question about the processes related to an intense emotion like panic: namely, what the relative contributions of central and peripheral processes are to the subjective experience of panic.

Study objective

The primary objective of this study is to identify the distinct roles of the peripheral and central nervous system in the subjective experience of panic.

Study design

A double-blind, randomized, placebo-controlled within-subject design will be used.

Intervention

In 3 different sessions, participants will undergo one 35% CO2 inhalation per session, preceded by oral administration of atenolol, metoprolol or a placebo. Each participant will receive each condition, in a randomised order.

Study burden and risks

Atenolol and metoprolol are registered medicines with a good safety and side effects profile (e.g., low likelihood of fatigue, dizziness). In the current study, we will only use single oral dosages of the drugs, with concentrations below the clinically allowed maximum dosage, and therefore we expect no or only minor and short lasting side effects. CO2 inhalations are associated with short-lasting discomfort and potentially minor adverse events such as headaches. Participants will visit the laboratory on four occasions: 1) screening visit (checking eligibility, including a physical and psychological exam, CO2 test with brief questionnaires assessing fear, discomfort and panic symptoms), 2-4) testing days: CO2 test with brief questionnaires assessing fear, discomfort and panic symptoms, after oral administration of atenolol, metoprolol or placebo. Physiological parameters will be recorded during the whole session, and with more precision during the CO2 inhalation. The testing days will be planned about one week apart, each session will last about 2.5 hours. Assessments are non-invasive and do not harbour any risks. Given that the results of this study could lead to an (improved) intervention for PAs, the burden and risks are deemed to be justifiable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

18-55 years old, healthy subject, adequate sensitivity to CO2 (as tested in the screening)

Exclusion criteria

mental or physical disorder/illness, pregnant, relatives with panic disorder

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2021
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO

Date:	18-01-2021
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
CCMO	NL75335.068.20