Targeting fear memory by disrupting the process of reconsolidation: A new intervention for panic disorder.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON47318

Source
ToetsingOnline

Brief title
Reconsolidation Intervention for Panic Disorder.

Condition

- Anxiety disorders and symptoms

Synonym
Anxiety Disorder., Panic Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Intervention, Memory Reconsolidation, Panic Disorder., Propranolol

Outcome measures

Primary outcome

Individual scores on the Panic Disorder Severity Scale.

Presence of panic disorder according to DSM V criteria

Secondary outcome

Individual scores on the Panic Appraisal Inventory, Mobility Inventory, Body Sensations Questionnaire, and Agoraphobic Cognitions Questionnaire will be used as secondary study parameters. In addition, willingness to inhale 35% CO2 is used as a secondary study parameter.

Study description

Background summary

Several epidemiological studies confirm that anxiety disorders as a group are the most impairing and prevalent of chronic diseases in Europe and the United States. Cognitive behavioral therapy for anxiety disorders is the treatment of choice in clinical practice. However, CBT only eliminates fearful responding, leaving the original fear memory intact as is substantiated by the high percentages of relapse (i.e., up to 60%), even after apparently successful treatment. At the turn of this century a major breakthrough in neuroscience was achieved with the discovery that fear memory is not inevitably permanent, but can change when retrieved. Nader and colleagues demonstrated in rats that upon retrieval, consolidated memories may return to a labile state, requiring de novo protein synthesis for restabilization: a process referred to as 'memory reconsolidation' that offers a window of opportunity to permanently weaken fear memories with amnesic agents. Disrupting the process of memory reconsolidation by amnesic agents (e.g., the noradrenergic beta-blocker propranolol HCl) recently progressed from animals to healthy participants. The current study addresses the question whether disrupting fear memory reconsolidation by propranolol is effective in patients with panic disorder.

Study objective

Our aim is to test whether disrupting the process of fear memory reconsolidation is an effective as well as efficient intervention for patients with panic disorder. A secondary aim is to test whether the expected reduction in panic attacks and concomitant anxiety symptoms persists over time.

Study design

Double-blind (pill) and single-blind (gas inhalation) placebo-controlled.

Intervention

One of the following:

1. 35% CO2-enriched air inhalation followed by the administration of 40 mg propranolol.

2. A placebo-inhalation followed by the administration of 40 mg propranolol.

3. 35% CO2-enriched air inhalation followed by the administration of 40 mg pill placebo.

Study burden and risks

Participants are receiving a short treatment that is expected to diminish their panic symptoms. CO2-inhalation causes symptoms of arousal and fear, but these are of short duration and are harmless. Furthermore, there are no long-term effects of this inhalation. Based on the Summary of Product Characteristics we expect that propranolol will be well tolerated and do not anticipate any serious adverse events.

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

A primary diagnosis of panic disorder according to DSM-V.

Exclusion criteria

* other relevant treatment for panic disorder at the time of study - e.g., CBT
* diagnosis of psychosis
* use of psychotropic medication
* A current state of asthma or COPD, which necessitates medication use
* history of respiratory diseases (asthma or COPD in the past does not lead to exclusion)
* history of cardiovascular diseases or irregular heartbeat
* history of cerebrovascular diseases
* history of severe allergic reactions to propranolol, which necessitated hospitalisation
* cerebral aneurysm among first-degree relatives
* Heart rate < 60. If heart rate is between 55 and 60 bpm, but exceeds 60 bpm after a minute of moderate physical activity (2-step test), the participant can be included. A heart rate of <50 in participants who spend 7 hours or more per week engaged in physical exercise will be the resting heart rate limit. A heart rate of <50 will lead to immediate exclusion (no 2-step test).
* BP < 100/60 or BP > 180/100
* epilepsy
* any medication contra-indicative of the use of propranolol
* pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	To be generated by VUmc
Generic name:	Propranolol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	17-06-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-09-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2018

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2015-005338-23-NL
ClinicalTrials.gov	NCT:NCT02631694
CCMO	NL54871.018.15