Reconsolidation: a new intervention for traumatized healthcare workers.

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Whether disrupting reconsolidation by a noradrenergic β-blocker provides long-term relief of PTSD symptoms in traumatized healthcare workers.

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

Summary

ID

NL-OMON49882

Source
ToetsingOnline

Brief title
#healthworkers

Condition

- Anxiety disorders and symptoms

Synonym
posttraumatic stress disorder | trauma

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Stichting Life Sciences Health - TKI,TNO

Intervention

Keyword: healthcare workers, memory, PTSD, reconsolidation

Outcome measures

Primary outcome

Our primary output will be (a) the percent change in PTSD diagnosis and (b) the decrease in frequency and severity of PTSD symptoms, from baseline to post-treatment and follow-up.

Secondary outcome

Not applicable.

Study description

Background summary

Memory for traumatic experiences is particularly strong and resistant to change. However, recent years have witnessed rapidly emerging evidence for the plasticity of fear memories. Upon its retrieval memory may be rendered labile and vulnerable to the disruptive effects of amnestic agents: this process is referred to as *disrupting reconsolidation* and may point to a novel therapeutic strategy for the permanent reduction of fear in patients suffering from posttraumatic stress disorder.

Study objective

Whether disrupting reconsolidation by a noradrenergic β-blocker provides long-term relief of PTSD symptoms in traumatized healthcare workers.

Study design

A non-concurrent multiple-baseline case-series design.

Intervention

A single reactivation session of trauma memory followed by the administration of 40 mg of the noradrenergic β-blocker propranolol.

Study burden and risks

Patients are receiving a short treatment that is expected to diminish their

PTSD symptoms. Reliving the traumatic experience through sensory reality causes symptoms of arousal and fear, but these are of short duration and harmless. Exposing individuals to fear-inducing situations is common in treatment for PTSD. Based on the Summary of Product Characteristics we expect that propranolol HCl will be well tolerated and do not anticipate any serious adverse events.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. aged between 18 and 65 years;
2. a primary diagnosis of PTSD according to DSM-V
3. a score of > 20 on the Post-traumatic Symptom Scale at screening

Exclusion criteria

1. other relevant treatment for PTSD within 3 months before start of the study
2. start of new medication within 3 months before start of study
3. life-time psychosis
4. acute suicide risk
5. current state of asthma or COPD, which necessitates medication use
6. cardiovascular diseases or irregular heartbeat
7. hypotension or hypertension
8. pregnancy or breastfeeding
9. epilepsy
10. any medication contra-indicative of the use of propranolol

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	te genereren door farmaceutisch bedrijf
Generic name:	propranolol hydrochloride
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	03-08-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-10-2020
Application type:	First submission
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	EUCTR2020-003563-26-NL
CCMO	NL74799.018.20