A pill against anxiety

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28388

Source
Nationaal Trial Register

Health condition

Dental anxiety

Sponsors and support

Primary sponsor: Academic Medical Center of the University of Amsterdam
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Dental trait anxiety score reduction from baseline to 4-weeks follow-up.

Secondary outcome

Self-reported anxiety during surgery; physiological parameters (heart rate and blood pressure) during recall of the crucial fear-related memory; self-reported vividness and emotional charge of the crucial fear-related memory.

Study description

Background summary

Background: Tooth and molar removals are among the most strongly feared procedures in dentistry and oral and maxillofacial surgery. Fear of extractions not only produces discomfort to the patient, but may also induce patient behavior that impedes surgery, thereby increasing operative time and complicating postoperative recovery. In addition, it has been found that undergoing an extraction poses a significantly increased risk for the development of chronic apprehension for dental surgical procedures, disproportionate forms of dental anxiety (i.e., dental phobia), and symptoms of post-traumatic stress. Evidence suggests that intrusive emotional memories of these events both induce and maintain these forms of anxiety. Addressing these problems effectively requires an intervention that durably reduces both the intrusiveness of key fear-related memories, and state anxiety during surgery. There is evidence to suggest that propranolol is capable of inhibiting “memory reconsolidation” (i.e., to block the process of storing a recently retrieved fear memory). Hence, the purpose of this trial is to determine the anxiolytic and fear memory reconsolidation inhibiting effects of the ß-adrenoreceptor antagonist propranolol on patients with high levels of fear in anticipation of a dental extraction.

Methods: Trial design: Multicenter, randomized, placebo-controlled, two-group, parallel, double-blind trial of 34 participants. Population and recruitment: Consecutive patients, referred by their dentist to the departments of oral and maxillofacial surgery of a University hospital and a secondary referral hospital in the Netherlands, for at least two tooth and/or molar removals, with self-reported high to extreme fear in anticipation of a dental extraction. Intervention: Two 40 mg propranolol capsules one hour prior to a dental extraction, followed by one 40 mg capsule directly postoperatively. Comparator: Placebo capsules. Primary outcome: Dental trait anxiety score reduction from baseline to 4-weeks follow-up. Secondary outcomes: Self-reported anxiety during surgery; physiological parameters (heart rate and blood pressure) during recall of the crucial fear-related memory; self-reported vividness and emotional charge of the crucial fear-related memory.

Discussion: This randomized trial is the first to test the efficacy of 120 mg of perioperative propranolol versus placebo in reducing short-term (‘state’) anxiety during dental extraction, fear memory reconsolidation, and lasting dental (‘trait’) anxiety in a clinical population. If the results show a reduction in anxiety, this would offer support for routinely prescribing propranolol in patients who are highly fearful of undergoing a dental extraction.

Study objective

The primary aim of this study is to determine whether administration of the active substance (two 40 mg propranolol capsules one hour prior to dental extraction, followed by one 40 mg capsule directly postoperatively) results in a significantly greater reduction of dental trait

anxiety in patients with self-reported high to extreme fear in anticipation of dental extraction, compared to the effects of the placebo comparator, from baseline to 4-week follow-up appointment.

To determine whether the use of propranolol in patients with high self-reported levels of fear in anticipation of tooth or molar removal results in:

(1) a significantly greater reduction of self-reported intraoperative (state) anxiety, compared to the placebo comparator, from baseline to 4-week follow-up appointment;

(2) a significantly greater decrease of physiological responding during recall of the crucial fear-related memory in, compared to the placebo comparator, from baseline to 4-week follow-up appointment;

(3); a significantly greater loss of specific phobia diagnoses, compared to the placebo comparator, from baseline to 4-week follow-up appointment;

(4) a significantly greater reduction of self-reported vividness and emotional charge of the crucial fear-related memory scores, compared to the placebo comparator, from baseline to 4-week follow-up appointment.

Study design

t=0 screening

t=1 first dental extraction procedure

t=2 follow up: second dental extraction procedure 4 weeks later

Intervention

Two 40 mg propranolol capsules one hour prior to a dental extraction, followed by one 40 mg capsule directly postoperatively.

Comparator: Placebo capsules.

Contacts

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Eligibility criteria

Inclusion criteria

1. Signed written informed consent

2. Minimum age of 18 years on entry to the study

3. Self-reported high to extreme fear of tooth or molar removal

4. Dutch or English-speaking

Exclusion criteria

1. Asthma or other obstructive pulmonary disease

2. Cardiac failure

3. Cardiac arrythmia

4. Renal failure

5. Insulin-dependent diabetes mellitus

6. Pregnant or breast-feeding

7. Current use of another ß-adrenoreceptor antagonist

8. Current use of anxyiolytic or antidepressant medication

9. Currently in psychotherapy for dental anxiety

10. Systolic blood pressure < 100 mmHg

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-11-2014
Enrollment:	34
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-08-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45112
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5216
NTR-old	NTR5364
CCMO	NL42210.018.13
OMON	NL-OMON45112

Study results

Summary results

Brunet A, Orr SP, Tremblay J, Robertson K, Nader K, Pitman RK: Effect of post-retrieval propranolol on psychophysiologic responding during subsequent script-driven traumatic imagery in post-traumatic stress disorder. J Psychiatr Res 2008, 42:503–6.

Lonergan MH, Olivera-Figueroa LA, Pitman RK, Brunet A: Propranolol's effects on the consolidation and reconsolidation of long-term emotional memory in healthy participants: a meta-analysis. J Psychiatry Neurosci 2013, 38:222–31.