The effects of propranolol on fear of wisdom tooth removal: A randomized, placebo-controlled, double-blind, parallel design trial

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27619

Source
NTR

Health condition

Dental phobia / Odontophobia / Specific phobia, blood-injection-injury type

Sponsors and support

Primary sponsor: Academical Center for Dentistry Amsterdam (ACTA)
Source(s) of monetary or material Support: Academical Center for Dentistry Amsterdam (ACTA)

Intervention

Outcome measures

Primary outcome

- emotional intensity and vividness of traumatic memory
- state anxiety
- trait anxiety

- heart rate, blood pressure

Secondary outcome

- PTSD-sympom severity and dental phobia

Study description

Background summary

Growing evidence suggests that beta-blocking agents reduce fearful memory. The current study aims to evaluate the effects of propranolol in the treatment of dental fear and phobia.

Research objectives are to evaluate the effect of propranolol (120 mg) in dental anxiety on:

1. Emotional arousal during treatment;

2. Emotional intensitity of traumatic memory of (a) the phobia's core traumatic event (b) the latest dental treatment;

3. Dental phobia in the long term.

Study objective

We hypothesize that subjects taking propranolol (1h preoperative and directly postoperative) will report:
1. lower levels of state anxiety
2. lower levels of dental trait anxiety
3. lower levels of aversive traumatic memory
4. lower levels of physiological arousal before a next procedure

Study design

Patients are assessed at three time points:
1. Shortly before and after the first treatment sessions (day 1);
2. Shortly before and after the second treatment session (day 30).

Intervention

At day one:
Third molar removal:

1. Propranolol 80 mg prior to, and 40 mg directly after treatment, or;
2. Placebo 80 mg prior to, and 40 mg directly after treatment.
At day 30: Third molar removal.

Contacts

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Eligibility criteria

Inclusion criteria

1. Excessive anxiety for necessary third molar extraction;
2. Age above 18 years.

Exclusion criteria

1. Systolic blood pressure < 100mmHg;

2. Allergic asthma, Decompensatio cordis, Cardiac arrythmia or Insulin-dependent diabetes;

3. Previous adverse reaction to a beta-blocking agent;

4. Use of another beta-blocking agent;

5. Pregnant or breast feeding;

6. Being in psychotherapy elsewhere;

7. Renal failure.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-03-2014
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL2272
NTR-old	NTR2398
Other	METC AMC / CCMO : 10/062 / NL31184.018.10 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A