

SOCIAL-EMOTIONAL BEHAVIOUR IN MALE PSYCHOPATHS AFTER DOUBLE-BLIND PLACEBO-CONTROLLED ADMINISTRATION OF INTRANASAL OXYTOCIN

Published: 02-04-2012

Last updated: 26-04-2024

Fundamental research with the objective to gain more insight in empathic processes within people suffering from psychopathy. Goal is to evaluate if affective empathic can be temporarily altered (in terms of minutes).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON39859

Source

ToetsingOnline

Brief title

BEHAVIOUR_RESPONSES_AFTER_OT/1.5

Condition

- Other condition

Synonym

psychopathy; empathy

Health condition

Persoonlijkheidsstoornis (psychopathie)

Research involving

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Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: Fonds Economische Structuurversterking

Intervention

Keyword: Empathy, Oxytocin, Psychopathy, Social Behaviour

Outcome measures

Primary outcome

- Reading the Mind in the Eyes Test (Baron Cohen, 2001);
- Subjective feelings of affective empathy on a Visual Analogue Scale, conform the Multifaceted Empathy Test (MET; Dziobek et al., 2008);
- Facial electromyographic (EMG) mimicry recording of the zygomaticus major and the corrugator supercilii muscle activity, following basic emotion inducing film fragments,

Secondary outcome

The equilibrium of the parasympathetic and sympathetic nerve system will be measured in terms of heart rate, respiration and skin conductance;

Saliva sampling before and after test procedures, reflecting baseline functioning of the HPA-axis (cortisol) and HPG-axis (testosterone and estradiol).

Study description

Background summary

Psychopathy is a personality disorder persisting through the lifespan. It

encompasses disturbances in the emotional, interpersonal and behavioral domains. Psychopathy is operationally defined by the Psychopathy Checklist-Revised Version (PCL-R; Hare, 1991, 2003). Participants are fully aware of their diagnosis of psychopathy.

A major component of psychopathy is an empathic disfunctioning. Empathy is a multidimensional construct that plays an important role in social understanding and social relationships. According to Soderstrom (2003) psychopathy should be regarded an empathy disorder. As there is growing evidence that the nonapeptide oxytocin is involved in the processing of cognitive empathy it is hypothesized that application of oxytocin in male psychopaths will lead to a temporarily improvement of the psychopath's affective empathy, too.

Study objective

Fundamental research with the objective to gain more insight in empathic processes within people suffering from psychopathy. Goal is to evaluate if affective empathic can be temporarily altered (in terms of minutes).

Study design

The study follows a within-subjects, double-blind, counterbalanced placebo-controlled design in male in-patients with psychopathy. Subjects will participate in both experimental and placebo condition of which the order is counterbalanced. Time period between sessions will be at least one week.

Intervention

Procedures on both days are identical and consist of an explanation of the tasks to be performed, the intranasal administration of either placebo or OT followed by neuropsychological tests displayed on a computer screen whilst physiological data are obtained.

Participants will be invited to undergo saliva sampling of indices of HPA-axis (i.e. cortisol) and HPG-axis (i.e. testosterone and estradiol) on the two trial days.

Study burden and risks

No burden or risks to be expected.

Contacts

Public

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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

- MALE SEX;;- DIAGNOSIS OF PSYCHOPATHY ACCORDING TO PSYCHOPATHY CHECKLIST - REVISED;;- GOOD PHYSICAL HEALTH;;- AGE BETWEEN 18 AND 60;;- NORMAL OR CORRECTED TO NORMAL VISION; ; - INTELLIGENCE NO LESS THAN BORDERLINE INTELLCTUAL FUNCTIONING.

Exclusion criteria

- OVERSENSITIVITY FOR OXYTOCIN OR CARRIER;;- COLOUR BLINDNESS;;- ILLITERATE OR INSUFFICIENT KNOWLEDGE OF DUTCH LANGUAGE;;- USE OF SSRI'S, MOOD STABILIZERS (E.G. LITHIUM), ANTIPSYCHOTICS OR HORMONAL TREATMENT FOR LIBIDO INHIBITION;;- USE OF ALCOHOL OR RECREATIONAL DRUGS WITHIN LAST 24 HOURS;;- CURRENT PSYCHOTIC DISORDER;;- CURRENT SEVERE DEPRESSIVE DISORDER;;- CURRENT SEVERE ANXIETY DISORDER;;- COMMON COLD WITH SEVERE RUNNING NOSE, CURENTLY OR WITHIN PREVIUOS SEVEN DAYS;;- HISTORY OF NEUROLOGICAL TREATMENT OF BRAIN STRUCTURES OR CURRENT NEUROLOGICAL TREATMENT;;- HISTORY OF ENDOCRINOLOGICAL TREATMENT OR CURRENT ENDOCRINOLOGICAL TREATMENT;;- HISTORY OF SEVERE CLOSED HEAD INJURY WITH LOSS OF CONSCIOUSNESS >15 MINUTES;;- PATIENT'S LEGAL INCAPACITY

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Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	21-11-2013
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Syntocinon
Generic name:	oxytocin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO	
Date:	02-04-2012
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	14-06-2012
Application type:	First submission
Review commission:	METC NedMec

Approved WMO
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Date:	12-05-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	23-06-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	17-10-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	17-11-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	10-07-2015
Application type:	Amendment
Review commission:	METC NedMec

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	EUCTR2010-024432-42-NL
CCMO	NL35148.041.12