The role of testosterone in social decision-making - An exploratory investigation into the effects of testosterone on human brain and behavior

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Primary objective: To identify the neural mechanisms via which testosterone modulates social decision-making. Secondary objectives: - To provide an extension of observed behavioral effects of testosterone on decision-making, specifically to examine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON36724

Source
ToetsingOnline

Brief title
The role of testosterone in social decision-making

Condition

- Personality disorders and disturbances in behaviour

Synonym
antisocial personality disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: behavior, brain, decisions, testosterone

Outcome measures

Primary outcome

Brain BOLD signal as measured with functional magnetic resonance imaging (fMRI)

- Behavioral performance on computerized tasks - Subjective measurements on

self-report questionnaires.

Secondary outcome

N/A

Study description

Background summary

Animal studies showed that the steroid hormone testosterone plays an important role in social behavior. Recent evidence suggests that testosterone is involved in human social behavior as well. Testosterone administration in humans has been reported to enhance social dominance and reduce anxiety, but findings have been inconsistent. Further, knowledge on how testosterone affects the brain mechanisms underlying social behavior is scarce. The main objective of our research is therefore to develop insights into how testosterone modulates the neural correlates of interactive social decision-making.

Study objective

Primary objective: To identify the neural mechanisms via which testosterone modulates social decision-making. Secondary objectives: - To provide an extension of observed behavioral effects of testosterone on decision-making, specifically to examine decisions made in a social context - To identify whether testosterone is involved in social risk-taking or in risk-taking in general - To evaluate whether the effect of testosterone on social

decision-making is moderated by personality variables - To contribute to a better understanding of the neuroendocrine systems underlying social mental disorders

Study design

Participants will be tested in a randomized, double-blind, placebo controlled, between-group design. Participants will receive either testosterone or a similar placebo dose and perform computerized tasks in an MRI scanner. Brain images will be used to identify the effects of testosterone on the neural correlates of social decision-making. After scanning, participants will complete several self-report questionnaires.

Intervention

One group of participants will receive .5 mg of testosterone through sublingual administration, and the other group will receive a similar dose of placebo.

Study burden and risks

The low dose of testosterone can be administered safely to humans without any relevant risk of serious adverse events. On both the day prior to the test session and on the day of the test session itself participants will adhere to some simple restrictions with respect to medication, alcohol and drug intake. During the morning of the test session participants will refrain from smoking and consuming stimulant-containing drinks. The risk associated with participation can be considered negligible and the burden can be considered minimal. No adverse events are expected and side effects of the treatment are very unlikely.

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

Healthy female volunteers between 18 and 35 years of age - Predominant right-handedness - Body mass index between 18.5 and 25

Exclusion criteria

Metal objects in or around the body - Claustrophobia - History of psychiatric treatment or current psychiatric treatment - History of neurological treatment or current neurological treatment - History of endocrine treatment or current endocrine treatment - History of heart-related disease - Regular use of corticosteroids -Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2011
Enrollment:	48
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-04-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL34927.091.10