PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Role of the nicotinic cholingergic System in top down and bottom up control of attention

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Aim of the study is to investigate the role of the neurotransmitter acetylcholine in attention. Three experiments will be performed using an attentional task while volunteers receive either nicotine or placebo. Nicotine acts on one of the receptors for the neurotransmitter acetylcholine. In the first experiment, we will investigate effects of nicotine on reaction times, in the second on brain activity using functional magnetic resonance imaging (fMRI). Further, the role of a variation in a nicotinic receptor gene will be investigated. Finally we will use transcranial magnetic stimulation (TMS) to pertub brain areas and investigate the effects of such pertubation on attention. In sum, the study should contribute to our understanding of the neurotransmitter acetylcholine in attention.

Brief Summary in Scientific Language

Aim of the study is to investigate the role of the cholinergic neurotransmitter system in attention. We aim to combine pharmacological and genetic neuroimaging approaches. Three experiments will be performed using a visual search paradgim with varying demands on top down and bottom up attentional control. We will use the cholinergic agonist nicotine, to experimentally manipulate cholinergic neurotransmission. The role of the nicotinic receptor gene CHRNA4 will be investigated. Behaviourally we will assess reaction times. Neurally we will measure BOLD responses by means of fMRI. Finally we will use TMS to pertub brain areas in a genotpye-specific way. In sum, the study should contribute to our understanding of neurochemical modulation of attention.

Organizational Data

- DRKS-ID: **DRKS00004529**
- Date of Registration in DRKS: **2012/11/13**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
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DRKS-ID: **DRKS00004529**
Date of Registration in DRKS: **2012/11/13**
Date of Registration in Partner Registry or other Primary Registry: **[---]***
Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **CT012010 , Ethik-Kommission der Deutschen Gesellschaft für Psychologie**

Secondary IDs

Health condition or Problem studied

- Free text: **healthy volunteers**

Interventions/Observational Groups

- Arm 1: **NiQuitin 7mg (GSK patch) 1 x 50 min**
- Arm 2: **placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Double or multiple blind**
- Who is blinded: **[---]***
- Control: **Placebo**
- Purpose: **Basic research/physiological study**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Comparison nicotine-placebo. It is one measurement after acute application of the drug. Primary endpoint in fMRI is a significant change in BOLD activity in parietal cortex, on the behavioural side it is a significant change in reaction times in the experimental paradigm.

Secondary Outcome

Comparison nicotine-placebo. It is one measurement after acute application of the drug. Secondary endpoint in fMRI is a significant change in BOLD activity in frontal and temporal cortex, on the behavioural side it is a significant change in accuracy and variability of reaction times in the experimental paradigm.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Universität, Oldenburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/05/02**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **40 Years**

Additional Inclusion Criteria

MR compatible, healthy

Exclusion criteria

neurological or psychiatric disease, metal in body, intake of drugs, smoker, left handed

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Deutsche Forschungsgemeinschaft (DFG)

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53275 Bonn
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*