



Trial Description

Title

Dopaminergic and cholinergic modulation of oculomotor control during saccades

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In this basic science study we investigate the role of the neurotransmitters Dopamine and Acetylcholine in the oculomotor control of healthy participants. We manipulate the level of Dopamine and Acetylcholine using drugs from daily clinical routine and apply placebo as a control condition. After administration of a single dose of a substance, participants perform a series of behavioral tasks on a computer. We measure their eye movements and use mathematical models to describe them. We then investigate the role of Dopamine (or Acetylcholine) by probing which parameters of the mathematical model capture effects of the different neurotransmitter systems.

Brief Summary in Scientific Language

Currently, it is not known how dopamine and acetylcholine modulate eye movements and corollary discharges during saccades. We plan to investigate the role of these two neuromodulators during eye movements while healthy subjects perform eye movement tasks. For this purpose, we plan to use approved drugs of common clinical use and minimal side effects in a placebo-controlled single dose pharmacological challenge with cross-over design.

Organizational Data

- DRKS-ID: **DRKS00008765**
- Date of Registration in DRKS: **2015/06/11**
- 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.: **KEK-ZH-Nr. 2014-0246 , Kantonale Ethikkommission des Kantons Zürich, Zürich, Schweiz**

Secondary IDs



Health condition or Problem studied

- Free text: **Healthy participants**

Interventions/Observational Groups

- Arm 1: **Healthy participants, pharmacological challenge (single dose) with Madopar® 250 mg vs. placebo (lactose). Followed by eye movement tasks. Modelling of data with mathematical models.**
- Arm 2: **Healthy participants, pharmacological challenge (single dose) with Reminyl® 8mg vs. placebo (lactose). Followed by eye movement tasks. Modelling of data with mathematical models.**
- Arm 3: **Healthy participants, no substance. Eye movement tasks. Modelling of data with mathematical models.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Placebo, Control group receives no treatment**
- Purpose: **Basic research/physiological study**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Goal of the study: Understanding how neuromodulators modulate the control of saccadic eye movements. Modelparameters of eye movement models will be compared statistically between drug and placebo conditions.

Secondary Outcome

[---]*

Countries of recruitment

- **CH Switzerland**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/06/30**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **40 Years**

Additional Inclusion Criteria

- **Age: ≥ 18 and ≤ 40 years**
- **Male sex**
- **European ancestry**
- **Written informed consent**
- **Consent to adhere to the study protocol**
- **Ability to adhere to the study protocol**

Exclusion criteria

General:

- **Serious past or present brain disease, brain injury or brain surgery**



- **Prostate or bladder disorder**
- **Glaucoma**
- **Asthma or other obstructive respiratory disease**
- **Current medication known to interact with levodopa, benserazide, or galantamine**
- **Allergy to lactose, levodopa, benserazide, or galantamine**

Addresses

■ Primary Sponsor

**Translational Neuromodeling Unit, Institut für Biomedizinische Technik,
Universität Zürich und ETH Zürich
Mr. Prof. Klaas Enno Stephan
Wilfriedstrasse 6
8032 Zürich
Switzerland**

Telephone: [---]*

Fax: [---]*

E-mail: **stephan at biomed.ee.ethz.ch**

URL: [---]*

■ Contact for Scientific Queries

**Translational Neuromodeling Unit, Institut für Biomedizinische Technik,
Universität Zürich und ETH Zurich
Mr. Dr Jakob Heinzle
Wilfriedstrasse 6
8032 Zürich
Switzerland**

Telephone: **+41446349122**

Fax: [---]*

E-mail: **heinzle at biomed.ee.ethz.ch**

URL: [---]*

■ Contact for Public Queries

**Translational Neuromodeling Unit, Institut für Biomedizinische Technik,
Universität Zürich und ETH Zurich
Mr. Dr Jakob Heinzle
Wilfriedstrasse 6
8032 Zürich
Switzerland**

Telephone: **+41446349122**

Fax: [---]*

E-mail: **heinzle at biomed.ee.ethz.ch**

URL: [---]*

Sources of Monetary or Material Support

■ Institutional budget, no external funding (budget of sponsor/PI)

Universität Zürich
Rämistrasse 71
8006 Zürich
Switzerland

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Study Closing (LPLV): **2017/06/30**

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.