

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

Trial Description

Title

Classical conditioning of intranasal insulin in healthy humans

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

We know that a number of hormones can be administered via the nose (intranasal administration) and thereby induce effects within the brain. We here examine the effects of the hormone insulin in the brain. On day 1, subjects were given a smell either combined with multiple administrations of intranasal insulin (in the experimental group) or with placebo (in the control group). On day 2, all subjects were given the smell and intranasal placebo. We here assess some of the putative insulin effects in the brain - i.e. its effects on food-intake, blood glucose and selected hormones, and memory. Moreover, we assessed whether the effects obtained under insulin can be learnt via Pavlovian conditioning when the stimulus previously signalling insulin (the smell) is combined with placebo in both groups at day 2. Conditioning means that the effects we obtained after insulin remain, when we present a placebo under the same environmental conditions that were prevalent when insulin was given. The most important results are reported when the study is published.

Brief Summary in Scientific Language

Insulin receptors are localized within the brain - with highest density in the olfactory bulbs, the hypothalamus, hippocampus, the amygdalae, and in the cerebral cortex. By intranasal administration, insulin can be transported into the central nervous system (CNS), reaching these receptors while maintaining euglycemia. Thus, the effect of insulin - unconfounded by hypoglycemia - can be examined. In the present study we compare insulin vs. placebo-treated subjects: On day 1, subjects were given a smell either combined with multiple administrations of intranasal insulin (in the experimental group) or with placebo (in the control group). On day 2, all subjects were given the smell and intranasal placebo. We examine the following questions addressing features of the CNS profile of insulin in healthy, normal-weight men. Does intranasal insulin 1. reduce food-intake and affect the interoception of hunger, 2., induce systematic effects in peripheral blood glucose, peripheral insulin, leptin, cortisol, and catecholamines within the euglycemic range, 3 affect memory performance, 4. can the insulin-induced effects be learnt by classical (Pavlovian) conditioning. If Pavlovian

conditioning occurred, subjects should demonstrate insulin-like responses when receiving a placebo in the so far insulin-associated environment. Results will be inserted here after publication of the study.

Organizational Data

- DRKS-ID: **DRKS00000537**
- Date of Registration in DRKS: **2010/09/15**
- 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.: **1444 , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

Secondary IDs

- BfArM-No.: **4015304**

Health condition or Problem studied

- Free text: **We examined only healthy subjects**
Application for prevention and treatment of adiposity might be considered

Interventions/Observational Groups

- Arm 1: **Intranasally administered insulin (6X 20 international units IU)**
- 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: **Parallel**
- Phase: **I**

Study Type: **Interventional**

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Allocation: **Randomized controlled trial**

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Who is blinded: [---]*

Control: **Placebo**

Purpose: **Basic research/physiological study**

Assignment: **Parallel**

Phase: **I**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

Food-intake behavior (calorie intake) as a reduction in a standardized test meal in the experimental- compared to the control group;

Blood glucose and peripheral insulin under euglycemia: Relative to baseline: cumulative change of blood glucose (11 measurement points) and insulin (6 measurement points) in the experimental- compared to the control group

Secondary Outcome

Peripheral leptin, cortisol, epinephrine, norepinephrine: Cumulative change of the hormones in the experimental- compared to the control group (measurement points see insulin)

Memory: Scores in psychometric test (Lern- und Gedächtnistest LGT-3) in the experimental- compared to the control group;

EEG: acoustically-evoked potentials in the experimental group compared to the control group (1 measurement point baseline, 3 measurement points during intranasal treatment)

Countries of recruitment

- **DE Germany**

Locations of Recruitment



Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **1999/10/07**
- Target Sample Size: **32**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **20 Years**
- Maximum Age: **30 Years**

Additional Inclusion Criteria

healthy male students

Exclusion criteria

Diabetes (also parents and siblings), allergies, chronic and/or acute rhinitis, diseases and anatomic deviations of the nose, chronic diseases: i.e., cardiovascular disorders; endocrine disorders and neurological diseases, especially seizures, chronic diseases of liver and kidneys, and other chronic diseases; medication with glucocorticoids and psychopharmacological drugs, substance abuse (alcohol, drugs); smoking; athletes were excluded

Addresses

■ Primary Sponsor

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duesseldorf.de/deutsch/unternehmen/kliniken/klinikfrendokrinologiediabetologieundrheumatologie/page.html

■ **Contact for Scientific Queries**

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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.)**

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Telephone: **0228-885-0**

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E-mail: **[---]***

URL: **[---]***

Status

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

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**Deutsches Register
Klinischer Studien**

German Clinical
Trials Register

Study Closing (LPLV): **2000/01/11**

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.*