Trial Description

Title

Effects of oxytocin on patients with Borderline Personality Disorder

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**Main objective of the trial is to examine if oxytocin, compared to placebo shows any additional effect on the
therapy achievements (outcome) of patients with borderline personality disorder, who receive an in-patient
standard psychotherapy (Dialectical-behavioral-therapy, Marsha Linehan (2006)).
Secondary objectives :
Investigate if oxytocin compared to placebo enhances social trust and emotion recognition in patients with
borderline personality disorder.
Comparison of the effects of Oxytocin on patients with BPD and major depression.**

Brief Summary in Scientific Language

**RCT. Two substudies (clinical and experimental). Main objective of the trial is to examine if oxytocin, compared to placebo shows any additional effect on the
therapy achievements (outcome) of patients with borderline personality disorder, who receive an in-patient
standard psychotherapy (Dialectical-behavioral-therapy, Marsha Linehan (2006)).
Secondary objectives :
Investigate if oxytocin compared to placebo enhances social trust and emotion recognition in patients with
borderline personality disorder.
Comparison of the effects of Oxytocin on patients with BPD and major depression.**

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000604**
- Date of Registration in DRKS: **2010/11/19**
- 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.: **307/10 , Ethik-Kommission der Albert-Ludwig-Universität Freiburg**

Secondary IDs

- EudraCT-Number: **2010-020956-69**
- BfArM-No.: **4036755**

Health condition or Problem studied

- ICD10: **F60.31 - [generalization F60.3: Emotionally unstable personality disorder]**
- ICD10: **F33.1 - Recurrent depressive disorder, current episode moderate**

Interventions/Observational Groups

- Arm 1: **Syntocinon-Spray (Novartis)**

  active substance: Oxytocin

  4x singel dose of 24 I.U. (before the experiments)

  For the period of 8 weeks 3 x a day 20 I.U. (max. daily dose of 60 I.E.)
- Arm 2: **Placebo-Spray**

  same dose as arm 1

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Double or multiple blind**
- Who is blinded: **[---]***
- Control: **Placebo**
- Purpose: **Other**
- Assignment: **Factorial**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **Double or multiple blind**

Who is blinded: **[---]***

Control: **Placebo**

Purpose: **Other**

Assignment: **Factorial**

- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Symptom severity (Borderline-Symtom-List, Bohus et al., 2007)
- Number of criteria in DSM-IV
- Severity of depression (Beck-Depression-Inventory, Hautzinger et al., 1994)
- Frequency of self-injury
- Dropout (early therapy termination)

Secondary Outcome

- Emotion recognition
- social trust
- rejection sensitivity
- tension
- interpersonel problems
- impulsivity
- disosiation
- mood
- eye-tracking
- cortisol
- heart beat frequence

14 process messure Points

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2010/12/01**
- Target Sample Size: **250**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **50 Years**

Additional Inclusion Criteria

- Borderline personality disorder or major depression (clinical control group)
- 18 - 50 years of age
- Mini Mental Status Test > 27 (capacity to consent)

Exclusion criteria

- chronic or acute somatic health problems
- Schizophrenia
- Bipolar affective disorder
- pregnancy
- breast feeding
- neurological disorder
- allergy to antidegradants

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

Contact for Scientific Queries

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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting planned**
- 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.*