Trial Description

Title

Attentional processes and decision making in social interactions - Investigation of alterations in individuals with Borderline Personality Disorder and the relationship to different hormones

Trial Acronym

Social_Perception 2

URL of the trial

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Brief Summary in Lay Language

People extremely differ in their perception of social situations, in their attentional focus, and in their ability to make decisions within social Encounters. Former research has shown that hormones may strongly influence our behaviour in social situations and our interactions with others. This (EEG-) study investigates the influence of oxytocin on the perception of and the reaction to facial expressions. Oxytocin is a hormone that plays a crucial role in attachment, social relationships, and the recognition of emotions in others.

Brief Summary in Scientific Language

People extremely differ in how fast they react to visual stimuli in competitive situations. Former research has shown that different factors like the ability of our brain to regulate attentional and decision making processes and emotions. It has also been shown that hormones strongly influence our behaviour in social situations and our interactions with others. This (EEG-) study investigates the influence of oxytocin on the perception of and the reaction to facial expressions.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00009815**
- Date of Registration in DRKS: **2016/01/11**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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Date of Registration in DRKS: **2016/01/11**
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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-032/2015 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F60.31 - [generalization F60.3: Emotionally unstable personality disorder]**
- Free text: **Healthy Volunteers**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>BPD-Oxytocin condition: 25 female patients with BPD, one intranasal Administration of 24 I.U. oxytocin; after clinical diagnostic interviews (International Personality Disorder Examination; Loranger et al. 1994 and SCID-I) as well as several dimensional questionnaires for the assessment of clinical symptoms and personality traits (Borderline-Symptom-Liste; Bohus et al., 2007; Zanarini Scale; Zanarini et al. 2003; German Version of the Difficulty in Emotion Regulation Scale; Gratz et al., 2004; German version of the Childhood Trauma Questionnaire; Bernstein et al., 1998; German version of the State-Trait Anger Inventory; Spielberger, 1991; German Version of the State-Trait Anxiety Inventory; Laux et al., 1981; German version of the Barrat Impulsivity Scale; Patton et al., 1995; Dissociation; Freyberger, 1999; Multidimensional Mood Questionnaire; Steyer et al. 1997; Rejection Sensitivity; Bungert et al., in press; Screening Questionnaire for Hormone Assessments; Schultheiss & Stanton,
2009; Life History of Aggression Inventory; Coccaro et al. 1997; Overt Aggression Sale Modified for Outpatients; OAS-M, Coccaro et al., 1991; Raven Matrices; Heller, 1981) one blood sample will be drawn for hormonal assessments. Participants will then be intranasally administered with 24 I.U. oxytocin or a placebo spray. In the following two Tasks, participants rate different facial expressions of a set of facial cues while an EEG is recorded.
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- Arm 2: **BPD-Placebo condition: 25 female patients with BPD, one intranasal Placebo Administration intranasal; see Arm 1 for procedure**
- Arm 3: **HC-Oxytocin condition: 25 female healthy volunteers; one intranasal Administration of 24 I.U. oxytocin; see Arm 1 for procedure**
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Arm 4: **HC-Placebo condition: 25 female healthy volunteers, one intranasal Placebo Administration intranasal; see Arm 1 for procedure**

Characteristics

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

Primary Outcome

Behavioral Data: Performance and reaction time; EEG: P1, N170, P300 for emotional faces after a single oxytocin vs. placebo administration in female BPD patients vs. healthy controls

Secondary Outcome

Exploratory correlations between behavioral and EEG data (see Primary outcome) and dimensional trait questionnaires (anger, German version of the State-Trait Anger Inventory; Spielberger, 1991; anxiety, German Version of the State-Trait Anxiety Inventory; depression, Beck Depression Inventory; aggressiveness, Life History of Aggression Inventory; Coccaro et al. 1997; Overt Aggression Sale Modified for Outpatients; OAS-M, Coccaro et al., 1991) after single oxytocin vs. Placebo Administration in female BPD patients vs. healthy volunteers.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Heidelberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/01/01**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **50 Years**

Additional Inclusion Criteria

General inclusion criteria: age 18-50 years, readiness for participation. Additional inclusion criterion for patients with Borderline Personality Disorder: Borderline Personality Disorder assessed with the International Personality Disorder Examination.

Exclusion criteria

General exclusion criteria: actual pregnancy, lifetime diagnosis of any psychotic or bipolar disorders, substance dependence during the past year, a history of brain damage, severe internistic or neurological disease, claustrophobia. Additional exclusion criterion for healthy controls: more than one DSM-IV criterion for Borderline Personality Disorder fulfilled.

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.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/12/31**

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.*