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

Trial Description

Title

Validating genomic biomarkers as risk markers for incidence, non-response and recurrence in depression - CAP Study

Trial Acronym

OptiMD-SP4 CAP

URL of the trial

[---]*

Brief Summary in Lay Language

Preliminary own work and findings of our partners point to a special significance of the blood-brain barrier gene ABCB1, the stress regulation gene FKBP5 and so-called "Gliotransmitter" genes P2RX4 and P2RX7 with respect to depression risk and antidepressant treatment outcome. Genomic indicators of the activity of these genes and their epigenetic modifications are promising candidates for serving as genomic biomarkers of depression, which will be validated in this program. There are three subprojects. The subproject considered here is called CAP study aiming to validate epigenetic biomarkers in regard to the risk of developing depression. A case/control study with 100 adolescents will be carried out, half of them suffering from depression (cases), while the other half will be negative for psychiatric disorders (controls). Saliva samples will be collected from both groups to obtain DNA. In addition, chemical modifications of the DNA (so-called epigenetic modifications) will be measured, which, unlike DNA, can be affected by environmental conditions and thereby might additionally contribute to the disease risk. We expect that both, genetic variations and epigenetic DNA modifications ciontribute to the disease risk. The aim of subproject is to identify those characteristics and to determine their contribution to the disease risk.

Brief Summary in Scientific Language

To validate epigenetic biomarkers for the disease risk of depression we are recruiting 50 adolescents with and 50 adolescents without diagnosis of acute depression for a case/control study. Clinical diagnosis will be optained using the Diagnostic Interview for Mental Disorders in Children and Adolescents (Kinder-DIPS). DNA will be extracted from saliva samples, genotyped and methylation rates of CpG-rich regions will be analyzed and compared between cases and controls. In particular, methylation rates of the following candidate genes are in the center of the analysis: ABCB1, FKBP5, P2RX4, P2RX5.

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

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[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00009819**
- Date of Registration in DRKS: **2016/01/13**
- 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.: **419-15 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**

Interventions/Observational Groups

- Arm 1: **Case/Control study comparing epigenetic modifications (DNA methylation) in CpG-rich regions within candidate genes (ABCB1, FKBP5, P2RX4, P2RX5) between adolescents with and without diagnosis of major depression.**
  DNA will be extracted from saliva samples, genotyped and methylation rates of CpG-rich regions will be analyzed and compared between cases and controls.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

Allocation: **Single arm study**

- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Case or control group assignment based on a detailed diagnosis using the Diagnostic Interview for Mental Disorders in Children and Adolescents (Kinder-DIPS). Genetic variations and DNA methylation rates in CpG-rich regions of the genes ABCB1, FKBP5, P2RX4 and P2RX7 will be determined as predictors of the case/control status.

Secondary Outcome

N.A.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center <style fontName='DejaVu Sans' isBold='true'>Klinik für Kinder & Jugendpsychiatrie, München</style>

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/01**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **8 Years**
- Maximum Age: **18 Years**

Additional Inclusion Criteria

Children and adolescents of both sexes aged 8 to 18 years, balanced in age and sex distribution between cases and controls; study consent of at least one parent or guardian of the study participant as well as oral and / or written consent of the minor study participant.

Exclusion criteria

Pervasive developmental disorder in study participants (ICD10 F84)

Addresses

- **Primary Sponsor**

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- **Collaborator, Other Address**

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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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URL: **www.bmbf.de**

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.*