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

Trial Description

Title

Effects of a Soy Lecithin Phosphatidylserine/ Phosphatidic Acid Complex (PAS) on Stress Reactivity in an Acute Stressful Situation (TSST – Trier Social Stress Test): a Randomized, Placebo – Controlled Single Center Study

Trial Acronym

PAS and Stress

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of this study is to investigate the effect of a nutritional supplement [Soy Lecithin phosphatidylserine/ Phosphatidic Acid Complex (PAS)] as compared to placebo on stress.
A total of 75 healthy non-smoking men aged 20-45 years take PAS/Placebo capsules for 42 consecutive days before finally taking part in a stress test. Stress will be assessed by means of questionnaires, measurements of heart rate and stress hormones in both the saliva and blood.

Brief Summary in Scientific Language

This is a randomized, double-blinded, placebo-controlled single-center study involving three treatment arms (placebo, 200 mg/day PAS, 400 mg/day PAS) in 75 non-smoking healthy men aged 20-45 years (25 subjects in each arm).
Subjects are randomly allocated to a treatment arm and administered 4 treatment capsules daily. Study Design: In total 4 study visits take place per subject. Subjects will be screened at V1 and if eligible will be included in the study at V2. At V2 the study participants will be randomly assigned to a treatment arm, complete baseline psychometric questionnaires to assess the chronic stress (Trier Inventory for Chronic Stress) and receive treatment supply. After 21 days of treatment, the subjects return to the study site (V3) and complete further stress questionnaires (Perceived Stress Scale and Depression Anxiety Stress Scales). V4 occurs after 42 days of treatment and the involves the completion of questionnaires, collection of physiological parameters and the TSST.

Organizational Data

- DRKS-ID: **DRKS00005125**
- Date of Registration in DRKS: **2013/08/26**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **837.542.12 , Ethik-Kommission bei der Landesärztekammer Rheinland-Pfalz**

Secondary IDs

Health condition or Problem studied

- Free text: **Stress-related impairments**
- Free text: **Healthy Volunteer**

Interventions/Observational Groups

- Arm 1: **PAS (Soy Lecithin Phosphatidylserine/Phosphatidic Acid Complex), 400 mg/day p.o. (capsules), for 42 days**
- Arm 2: **PAS (Soy Lecithin Phosphatidylserine/Phosphatidic Acid Complex), 200 mg/day p.o. (capsules), for 42 days**
- Arm 3: **Placebo, for 42 days**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Placebo, Active control (effective treament of control group)**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, investigator/therapist**

Control: **Placebo, Active control (effective treament of control group)**

Purpose: **Basic research/physiological study**

Assignment: **Parallel**

Phase: **N/A**

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

Primary Outcome

The Primary aim of the study is to assess the effects of two PAS dosages as compared to placebo on stress-induced saliva cortisol levels with regards to chronic stress level assessed through the Trier Inventory for Chronic Stress (TICS). After treatment for 42 consecutive days, saliva samples are collected from subjects during the TSST at the following intervals: 2 minutes prior to TSST and 1, 10, 20, 30 and 60 minutes post TSST. The salivary cortisol levels are then determined using a competitive solid phase time-resolved fluorescence immunoassay with fluorometric end point detection (DELFIA)(Dressendörfer et al., 1992).

Secondary Outcome

The secondary objectives of the study are to investigate the effects of the two PAS dosages as compared to placebo on general stress perception and the psychobiological stress response to the TSST with regards to chronic stress level.

The secondary outcome parameters are as follows:
1) General stress levels
a) Questionnaire: Trier Inventory for Chronic Stress (TICS) - at study enrolment (V1), and V4
b) Questionnaire: Perceived Stress Scale (PSS) - at V2, V3 and V4
c) Questionnaire: Depression and Anxiety Stress Scales (DASS) - at V2, V3 and V4
2) Mood before and after the TSST
a) Questionnaire: Multidimensional Mood State Questionnaire (MBDF) - at V4
b) Questionnaire: Profile of Moods States (POMS) - at V4
3) Stress Perception, anxiety and insecurity in relation to the TSST
a) Questionnaire: Visual Analogue Scales (VAS)- at V4
b) Questionnaire: State-Trait Anxiety (STAI-X1) - at V4
4) Serum Cortisol and Adrenocorticotropic Hormone (ACTH) levels in reponse to the TSST - at V4
a) Serum Cortisol in parallel to Saliva Cortisol sampling 1x pre-TSST and 5x post-TSST
b) ACTH 1x pre-TSST and 1x post-TSST
5) Cardiovascular Response to the TSST - at V4 (pre-, during-, post TSST; total of

55 min)
a) Heart Rate
b) Low frequency/High frequency (LF/HF)
c) Pulse and Transit Time (PTT)
6) Electrodermal activity (EDA) - at V4 (pre-, during-, post TSST)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Trier**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/01/16**
- Target Sample Size: **75**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **20 Years**
- Maximum Age: **45 Years**

Additional Inclusion Criteria

Healthy non–smoking male volunteers aged 20–45 years.

Exclusion criteria

Known allergies to ingredients of the test product; addiction to nicotine, drugs or alcohol; change in nutritional habits (start of a weight loss diet, overconsumption of caffeine); serious general illness, ongoing or within the last 12 months; febrile illness (> 24 h) within 7 days prior to assessment; antibiotics for the last four weeks before study inclusion; any known diseases as diabetes mellitus, heart disease, hypertension, kidney disease, significant respiratory disease, or epilepsy; any known immunologic or infectious disease (e.g. hepatitis, tuberculosis, HIV or AIDS, lupus, rheumatoid arthritis) which could place the subject at risk or interfere with the accuracy of the study results; current or past participation in a TSST study; employees of the Sponsor or the CRO; other medication that, in the opinion

of the Investigator is likely to affect their response to treatment; other condition the Investigator or their duly assigned representatives believes may affect the ability of the individual to complete the study or the interpretation of the study results.

Addresses

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/07/02**

Trial Publications, Results and other documents

- Paper <style fontName='DejaVu Sans' isBold='true'>Hellhammer, J., Vogt, D., Franz, N., Freitas, U. & Rutenberg, D. (2014). The soy-based phosphatidylserine/phosphatidic acid complex MemreePlus normalizes the stress reactivity of hypothalamus-pituitary-adrenal-axis in chronically stressed male subjects: A randomized, placebo-controlled study. Lipids in Health and Disease, 13 :121.</style>

** 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.*