## Trial Description

### Title

**Efficacy and safety of Neurodoron in patients with nervous exhaustion - a randomized, double-blind, placebo-controlled clinical trial -**

### Trial Acronym

[---]*

### URL of the trial

[---]*

### Brief Summary in Lay Language

The drug to be investigated in this trial, Neurodoron®, is approved in Germany for treatment of nervous exhaustion and convalescence with strengthening the metabolism and is available without prescription. The term “nervous exhaustion” describes a state of chronic exhaustion or fatigue where a physical cause cannot be identified, but with several characteristic symptoms being present that allow the diagnosis.

The presumed efficacy of Neurodoron® is currently based on information according to the “Commission C”, a consultative committee to the German Health Authority. This controlled trial is intended to further investigate the efficacy and safety of Neurodoron® in order to achieve a comprehensive evaluation of the drug. Women and men of at least 18 years suffering from nervous exhaustion for at least 3 months are eligible. The participants will be randomly allocated to one of two treatment groups, one of which being treated with Neurodoron® and the other with identical placebo tablets containing no active substance. The entire treatment duration will be 6 weeks. During this time all participants take three (3x1) tablets of trial medication per day. During the 4 visits at the study centre questionnaires have to be completed in order to assess changes in symptoms of exhaustion, wellbeing and quality of life. In addition, changes in state of health are assessed and physical and laboratory (blood) investigations are carried out.

### Brief Summary in Scientific Language

Today, the term neurasthenia describes chronic exhaustion or fatigue without identifiable organic cause which is accompanied by several characteristic symptoms. For treatment of chronic exhaustion different strategies may come into consideration, encompassing (among others) cognitive and behavioural therapies, active exercise therapy or gradual increase of physical activity. However, a commonly recognized standard therapy does not exist. Nevertheless, medical treatment for alleviation of symptoms is possible. Characteristic symptoms such as nervousness, irritability, restlessness and sleep disorders may be controlled by herbal or homeopathic medicines. Different observational studies, e.g. with Neurodoron® have demonstrated this. The drug consists of gold (Aurum metallicum), Ferrum-Quartz and potassium dihydrogen phosphate. According to anthroposophic-medical understanding, these components boost self-regulation in stress situations, in particular harmonisation of spirit, mind and body.
the Commission C monograph, the drug is approved in Germany since 2007 for treatment of nervous exhaustion and convalescence with strengthening the metabolism. Results of an open-label, uncontrolled, non-interventional study show the effects of Neurodoron® in medical practice. Currently there are no controlled trials (e.g. in comparison with placebo) for Neurodoron®, thus a quantitative assessment of Neurodoron's efficacy is not yet possible. This randomized, double-blind and placebo-controlled clinical trial is intended to obtain data on efficacy and safety of Neurodoron® in a controlled setting.

The entire treatment duration in this study will be 6 weeks. During this time all participants take three (3x1) tablets of their trial medication per day. During the 4 visits at the study centre questionnaires have to be completed in order to assess changes in symptoms of exhaustion, wellbeing and quality of life. In addition, changes in state of health are assessed and physical and laboratory (blood) investigations are carried out.

Organizational Data

- **DRKS-ID:** DRKS00003261
- **Date of Registration in DRKS:** 2011/09/15
- **Date of Registration in Partner Registry or other Primary Registry:** [---]*
- **Investigator Sponsored/Initiated Trial (IST/IIT):** no
- **Ethics Approval/Approval of the Ethics Committee:** Approved
  - (leading) Ethics Committee Nr.: 11/0131 - ZS EK 14, Ethik-Kommission des Landes Berlin
- **EudraCT-Number:** 2010-024189-23
- **BfArM-No.:** 4037210

Secondary IDs

- **ICD10:** F48.0 - Neurasthenia
- **ICD10:** [---]* - [---]*

Health condition or Problem studied

Interventions/Observational Groups

- **Arm 1:** Brandname: Neurodoron
  1 tablet contains:
  - 83.3 mg Aurum met. praep. Trit. D10,
  - 83.3 mg Kalium phosphoricum Trit. D6,
  - 8.3 mg Ferrum-Quartz Trit. D2

  **Dosage and duration of treatment:** 3x1 tablet daily p. o. for 6 weeks

- **Arm 2:** Placebo tablets 3x1 daily p. o. for 6 weeks
Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Randomized controlled trial
- Blinding: Double or multiple blind
- Who is blinded: [---]*
- Control: Placebo
- Purpose: Treatment
- Assignment: Parallel
- Phase: IV
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

1. Difference of symptom-sumscore between beginning and end of treatment after 6 weeks via questionnaire

2. Perceived Stress, comparison of the results measured by the Perceived Stress Questionnaire (PSQ) at the beginning of treatment and after 6 weeks of treatment

3. General health status, measured by SF-36 at the beginning of treatment and after 6 weeks.

Secondary Outcome

1. Clinically relevant reduction in exhaustion, measured at baseline and after 6 weeks by the Tedium Measure according to Pines/Aronson/Kafry

2. Time until onset of significant improvement as noted by the patient by interview after 2 and further 4 weeks of treatment

3. Number of patients showing improvement of ≥50% of the symptom-sumscore after 6 weeks of treatment by calculating the symptom-sumscore at baseline and after 6 weeks of treatment and counting the number of patients whose symptom-sumscore has improved by ≥50%.

4. Number of dropouts in the treatment groups because of lack of efficacy and/or adverse reactions after 6 weeks of treatment by counting the affected patients

5. Safety: Changes in laboratory values haemogram with thrombocytes, electrolytes, CRP, ASPAT, ALAT, gamma-GT, creatinine, HbA1c between baseline and after 6 weeks of treatment by comparing the results of the laboratory values at baseline and after 6 weeks by listing the data with changes

6. Number, type and characeristics of adverse events after 6 weeks of treatment by counting the affected patients and assessing intensity and causality
Countries of recruitment

- DE Germany

Locations of Recruitment

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2011/09/05
- Target Sample Size: 182
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria

1. Informed consent
2. At least 18 years of age
3. Confirmed diagnosis of nervous exhaustion according to the definition for neurasthenia as laid down in the WHO-criteria for research, characterized by either A.1 or A.2:
   A.1 Persistent and distressing complaints of feelings of exhaustion after minor mental effort (such as performing or attempting to perform every-day tasks that do not require unusual mental effort),
   A.2 Persistent and distressing complaints of feelings of fatigue and bodily weakness after minor physical effort
   and B. at least one of the following symptoms:
   feelings of muscular aches and pains, dizziness, tension headaches, sleep disturbance, inability to relax, irritability.
C. Inability to recover from A.1 or A.2 by normal periods of rest, relaxation or entertainment.
D. The duration of the disorder is at least 3 months.
Exclusion criteria

1. Concurrent or previous participation in clinical trials with trial drugs or other treatments for nervous exhaustion

2. Known hypersensitivity against wheat starch

3. Organic disease responsible for exhaustion (e.g. known heart, kidney or liver disease, uncontrolled diabetes mellitus, infection, iron deficiency anaemia, hypothyreotic metabolic situation)

4. Neuro-psychiatric disease causing exhaustion (e.g. psychosis, schizophrenia, dementia)

5. Organic brain syndrome (e.g. postencephalitic syndrome, sequelae of traumatic brain injury)

6. Presumed major depression, defined by BDI-II (Beck Depression Inventory) ≥29

7. Presumed major panic disorder or generalised anxiety disorder defined by GAD-7-score ≥16

8. Concomitant medication interfering with IMP, e.g. other drugs for treatment of stress/exhaustion/burnout, antidepressants or benzodiazepines during the last 4 weeks, initiation of treatment with oral beta-adrenoreceptorblockers

9. Known alcohol or drug abuse or dependency

10. Placement in an institution due to official directive or judicial order

11. Pregnancy, lactation

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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Status

Recruitment Status: Recruiting complete, follow-up complete
Study Closing (LPLV): 2012/09/06

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.