PLEASE NOTE: This trial has been registered retrospectively.

Trial Description

Title

EUDOR-A Multi-centre Research Program
A Naturalistic, European Multi-centre Clinical Study of EDOR Test in adult patients with primary depression

Trial Acronym

EUDOR-A

URL of the trial


Brief Summary in Lay Language

Electrodermal activity refers to changes in the electrical conductance of the skin due to sweat gland activity. In research, electrodermal activity has been successfully used as indicator of emotional states, such as such as joy, sadness and fear. In addition, electrodermal reactions are evoked by information processing, such as problem solving, orienting behaviour and learning. Presentation of repeatedly identical non-significant stimuli elicits less and less reactions, a phenomenon known as habituation or “learning the usual”. Electrodermally hyporeactive individuals are those who show an unusual rapid habituation. That is a loss of the normal emotional and information processing reaction of interest of prosaic changes in the environment. Several studies reported an association between electrodermal hyporeactivity and suicidal tendencies, particularly among depressed patients.

The aim of the present study is to test the effectiveness and the usefulness of a new device (EDOR Test) to be used as an objective support in the suicide risk assessment of depressed patients.

Patients with a diagnosis of depression are recruited to the study. In the test, they are asked to put two fingers on two gold sensors placed on top of the device. During the test, a moderately strong tone is presented through headphones with long and varying intervals. The EDOR Test is able to register the changes in the electrical conductance of the skin in response to the tones. The severity of depressive symptoms, as well as current and past suicidal thoughts and attempts, are also assessed. Then, the recruited patients are followed-up for one year in order to monitor the occurrence of suicidal behaviour.

It is hypothesized that patients with strong indications of a wish to die, in a suicide attempt before or after the test or by suicide, mainly are electrodermally hyporeactive and that reactive patients will have few indications of a wish to die.

Brief Summary in Scientific Language

Introduction: Electrodermal reactivity (EDR) has been successfully used as indicator of interest, curiosity, including depressive states. The reactions depend on the quantity of sweat secreted by those eccrine sweat glands that are located...
in the hypodermis of palmar and plantar regions. Electrodermal hyporeactive individuals are those who show an unusual rapid habituation to identical non-significant stimuli. Previous findings suggested that electrodermal hyporeactivity has a high sensitivity (up to 97%) and high “raw” specificity, the same as negative predictive value, (up to 98%) for suicide.

Aims: To test the effectiveness and the usefulness of the EDOR Test (ElectroDermal Orienting Reactivity) in order to be used as a support in the suicide risk assessment of depressed patients. To investigate the association between electrodermal hyporeactivity measured through the EDOR Test and intentional self-harm (i.e., suicide and suicide attempt), with and without death intent and with and without violent method, in adult patients with a primary diagnosis of depression.

Methods: 1500 patients with a primary diagnosis of depression, also in remission, will be recruited. Depressive symptomatology is evaluated through the Montgomery-Asberg Depression Scale. Previous suicide attempts are registered and the death intent of the worst attempt is rated according to the first eight items of the Beck Suicide Intent Scale. The suicide risk is also assessed according to rules and traditions at the centre. The EDOR Test is finally performed. During the EDOR Test, two fingers are put on gold electrodes and DC of 0.5 V is passed through the epidermis of the fingers according to standards. A moderately strong tone is presented through headphones now and then during the test. The electrodermal responses to the stimuli represent an increase in the conductance due to the increased number of filled sweat ducts that act as conductors through the electrically highly resistant epidermis. For ethical reasons, the suicide risk assessment can be revised based on the results of the EDOR Test. Each patient is followed up for one year in order to assess the actions of intentional self-harm occurred in this period, using the same above described method.

Expected results: Patients that in a suicide attempt reveals strong death intent or commit suicide will be electrodermally hyporeactive in most cases and non-hyporeactive patients will show only few indications of death intent or suicides.

Organizational Data

- **DRKS-ID:** DRKS00010082
- **Date of Registration in DRKS:** 2016/05/31
- **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.: N/A , Comitato Etico Indipendente Azienda Ospedaliero-Universitaria "Policlinico Consorziale"

Secondary IDs

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

ICD10: F31 - Bipolar affective disorder

ICD10: F34 - Persistent mood [affective] disorders

ICD10: F38 - Other mood [affective] disorders

ICD10: F39 - Unspecified mood [affective] disorder

Free text: Intentional Self-harm

Interventions/Observational Groups

Arm 1: Patients with a primary diagnosis of depression, also in remission, are recruited. Beside demographic information, the following clinical data are obtained:
- Primary and secondary psychiatric diagnoses according to ICD-10;
- Somatic diagnoses according to ICD-10;
- Alcohol and drug abuse;
- Pharmacological and psychological treatment;
- Actions of intentional self-harm during the last six weeks and lifetime;
- Suicide risk assessed according to rules and traditions at the centre.

The patients are also assessed through the Montgomery-Asberg Depression Scale. If actions of intentional self-harm occur, the death intent of the worst suicide attempt (according to the patient) is rated using the first eight items of the Beck Suicide Intent Scale. Finally, the patients undergo the EDOR Test (ElectroDermal Orienting Reactivity Test) to assess their level of orienting reactivity.

The participant is informed that the EDOR-test is studied as a new tool for helping doctors in assessing the risk of suicide in depressed patients. He/she is also informed that the results of the test will be interpreted by an international expert and then transmitted to his/her doctor. When the participants undergo the test they are not informed about the result.

Each patient is followed up for one year in order to assess the actions of intentional self-harm occurred in this period, using the same above described method.

Characteristics

- Study Type: Non-interventional
- Study Type Non-Interventional: Other
- Allocation: Single arm study
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Uncontrolled/Single arm
- Purpose: Screening
- Assignment: Single (group)
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A
Primary Outcome

In the current observational study, the primary variables to be investigated are:
- the prevalence of electrodermal hyporeactivity among the depressive patients, recruited and tested in the naturalistic setting of psychiatric clinics;
- the incidence of actions of intentional self-harm i.e., suicide after, and suicide attempt before and after test during the one-year follow-up period.

It is hypothesized that the EDOR Test will identify electrodermal hyporeactive depressed patients who in turns will show a higher suicidal proneness as indicated by intentional self-harm behaviours.

The electrodermal reactivity is assessed through the EDOR Test when the patient is enrolled in the study.

The occurrence of intentional self-harm during the one-year follow-up period will be assessed. Information on the method/s used will be obtained and the correspondent ICD-10 code/s will be assigned. The death intent of the worst suicide attempt (according to the patient) will be evaluated using the first eight items of the Beck Suicide Intent Scale.

Secondary Outcome

Secondary outcomes to be assessed will be:
- the influence of secondary psychiatric diagnoses, antidepressive treatments, somatic diagnoses, as well as demographic characteristics, such as age and gender, on electrodermal reactivity levels;
- possible traces of influence on the rate of suicide by the clinical use of the EDOR Test.

Information on demographic characteristics, secondary psychiatric diagnoses, antidepressive treatments and somatic diagnoses will be collected immediately after patient’s enrolment.

If possible, information on the suicide rates at the participating centres during the last two years before the beginning of the study and during the one-year follow-up period will be gathered. Suicide rates in the centres’ region (at county level or similar) will be also taken in consideration.
DRKS-ID: **DRKS00010082**
Date of Registration in DRKS: **2016/05/31**
Date of Registration in Partner Registry or other Primary Registry: [---]*

## Countries of recruitment

- FR France
- DE Germany
- HU Hungary
- IT Italy
- PL Poland
- PT Portugal
- RO Romania
- ES Spain
- SE Sweden

## Locations of Recruitment

- University Medical Center Département d'Urgences et Post Urgences Psychiatriques. Centre Hospitalier Universitaire de Montpellier, Montpellier
- University Medical Center Klinik und Poliklinik für Psychiatrie und Psychotherapie, Universitätsmedizin Rostock, Rostock
- University Medical Center Universitätsklinik für Psychiatrie und Psychotherapie, Tübingen
- Medical Center NIPA (National Institute of Psychiatry and Addictions), Budapest
- University Medical Center Clinica Psichiatria, Ospedale S. Martino, Genova
- University Medical Center SC Psichiatria, Ospedale Maggiore della Carità, Novara
- University Medical Center Policlinico di Bari-Dipartimento di Psichiatria, Bari
- University Medical Center First Psychiatric clinic, Warszaw Medical University, Warsaw
- University Medical Center II Klinika Psychiatryczna, Warsaw
- University Medical Center Centro Hospitalar de Lisboa Ocidental (CHLO), Lisbon
- University Medical Center Serviço de Psiquiatria, Hospital Egas Moniz, Lisbon
- University Medical Center Department of Clinical Psychology and Mental Health, Iuliu Hatieganu University of Medicine and Pharmacy Cluj-Napoca, Cluj-Napoca
- University Medical Center Centro de Salud Mental Moncloa, Madrid
- University Medical Center Area de Psiquiatría - Facultad de Medicina, Oviedo
- University Medical Center Psychiatric Neuromodulation Unit, Department of Clinical Sciences, Faculty of Medicine, Lund University, Lund
- Medical Center Öppenvårdsheten, Malmo

## Recruitment
Inclusion Criteria

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

Additional Inclusion Criteria

- In- and outpatients with a primary diagnosis of depression according to the ICD-10, also in remission;
- Age: 18 years or older;
- Gender: Any;
- Signed Informed Consent.

Exclusion criteria

- Patient’s dissent to participate in the study;
- In cases of diagnosed or suspected dementia, the patient should to be excluded unless there is a special interest by the centre. If included, this condition must be noted;
- In cases of known or suspected alcohol or other substance abuse, the patient has to be excluded unless there is a special interest by the centre. If included, this condition must be noted;
- Patient’s inability to understand the instructions for the EDOR Test;
- Serious problems of hearing.

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 continuing
- Study Closing (LPLV): [---]*
Trial Publications, Results and other documents


- Abstract - Marco Sarchiapone et al., EUDOR-A: a naturalistic, European multi-centre clinical study of EDOR Test in adult patients with primary depression. 23rd European Psychiatric Association (EPA) Congress, Vienna, Austria, 28-31 March 2015.

- Abstract - Marco Sarchiapone et al., EUDOR-A multi-centre research program: Electrodermal hyporeactivity, depression and suicide. XVI World Congress of Psychiatry, Madrid, Spain, 14-18 September 2014.

* 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.