

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

## Trial Description

### Title

**In-patient smoking cessation treatment in comorbid patients with other substance dependence**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**In Germany, in-patient smoking withdrawal is not covered by health insurances. As a consequence, nicotine-dependant patients are only admitted for a withdrawal of another substance. During their stay in clinic they should be motivated to withdraw from their nicotine-dependance as well.**

**In this study, we assess our current in-patient treatment program for comorbid patients who have a substance dependence and an additional nicotine dependence. All patients are included in the study, either in the continuous smoking arm or in the smoking cessation arm.**

**The smoking cessation program consists of motivational group therapy program, medical advice and smoking withdrawal medication such as nicotine replacement therapy, bupropione or varenicline. The medication is standard therapy. Patients are requested to fill out questionnaires at admission, 7 days after admission and at discharge and a telephone interview is scheduled 3 months after discharge to evaluate current smoking habits.**

**We want to evaluate whether our substance dependant patient can be also motivated to withdraw from nicotine in an in-patient setting which lasts 3 weeks and whether smoking cessation can be achieved in this population.**

### Brief Summary in Scientific Language

**A large number of patients with a substance dependence are also nicotine-dependant. The comorbidity of alcohol dependence and nicotine dependence amounts to 80%. 30% of these patients die before the age of 60 where nicotine dependence primarily accounts for organ damage and death.**

**Particularly patients with alcohol dependence were considered not to be motivated for nicotine dependence and that a withdrawal of both substances at the same time would be impossible or at least associated with increased levels of relapse. Based upon these assumptions, in-patient smoking cessation treatment was for a long time no standard therapy in patients who were admitted for another substance use disorder.**

**In Germany, in-patient smoking cessation therapy is further compromised since**

**health insurances only cover for smoking withdrawal therapy in the context of a withdrawal from another substance like alcohol or amphetamine. As a consequence, nicotine dependant patients are admitted for another substance disorder and need to be motivated to withdraw from nicotine as well on admission. In this study, we assess our current in-patient treatment program for comorbid patients who have a substance dependance and an additional nicotine dependance. All patients are requested to participate in the study, either in the continuous smoking arm or in the smoking cessation arm.**

**The smoking cessation program consists of a motivational group therapy program, medical advice and smoking withdrawal medication such as nicotine replacement therapy, bupropione or varenicline. The medication is standard therapy.**

**Patients are requested to fill out general and substance-specific questionnaires (FÄR, QSU, BSI, OCDS, SOKRATES-N, WHO-QOL-BREF, ADS, AASE, SCQ-A, FTND, SER-G, ISMI-R, STAI G Form X2, BDI, BIS-11, TCI, PSS)**

**at admission, 7 days after admission and at discharge and a telephone interview is scheduled 3 months after discharge to evaluate current smoking status.**

**Based upon the questionnaires and clinical interviews, we plan to assess the rate of smoking reduction and of smoking abstinence as well as the rate of abstinence from the other substance. We also want to define subgroups which profit most from therapy.**

**On a broader scale, we want to investigate whether our current smoking cessation program is reasonable to continue which require substantial numbers of patients willing to attempt smoking cessation within our program but also substantial abstinence rates at discharge and at the catamnesis timepoint.**

## Organizational Data

- DRKS-ID: **DRKS00003344**
- Date of Registration in DRKS: **2011/12/06**
- 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.: **2011-220N-MA , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **F17.2 - Mental and behavioural disorders due to use of tobacco; Dependence syndrome**
- ICD10: [---]\* - [---]\*

## Interventions/Observational Groups



- Arm 1: **smoking cessation therapy with combined psychotherapy and medication:**  
**Structured clinical interview and questionnaires on admission, on day 7, at discharge and 3 months after discharge via a telephone interview**
- Arm 2: **smoking cessation therapy with medication only:**  
**Structured clinical interview and questionnaires on admission, on day 7, at discharge and 3 months after discharge via a telephone interview**
- Arm 3: **smoking cessation therapy with psychotherapy only:**  
**Structured clinical interview and questionnaires on admission, on day 7, at discharge and 3 months after discharge via a telephone interview**
- Arm 4: **no treatment:**  
**Structured clinical interview and questionnaires on admission, on day 7, at discharge and 3 months after discharge via a telephone interview**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Active control, No treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]\*

## Primary Outcome

**Nicotine abstinence rate 3 months after hospital discharge**

## Secondary Outcome

- 1. Nikotine abstinence at discharge**
- 2. nicotine reduction at discharge compared to admission**
- 3. nicotine reduction 3 months after discharge compared to admission and discharge**
- 4. other substance abstinence 3 months after discharge**
- 5. rate of nicotine dependant patients who could be motivated to attempt smoking cessation during hospital stay.**
- 6. nicotine reduction/abstinence 3 months after discharge: group comparison of varenicline arm, nicotine replacement therapy arm, Bupropione arm, only cognitive psychotherapy arm, no therapy arm**
- 7. subgroup analysis of patient data for identification od patient subgroups profiting most from therapy program.**



## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/03/01**
- Target Sample Size: **200**
- 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

**nicotine dependance,  
other substance dependance**

## Exclusion criteria

**severe cognitive deficitis**

## Addresses

- **Primary Sponsor**

**Zentralinstitut für Seelische Gesundheit  
Klinik für Abhängiges Verhalten und Suchtmedizin  
Mr. Dr. med. Tillmann Weber  
J5  
68159 Mannheim  
Germany**



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#### ■ **Contact for Scientific Queries**

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## **Sources of Monetary or Material Support**

#### ■ **Institutional budget, no external funding (budget of sponsor/PI)**

**Klinik für Abhängiges Verhalten und Suchtmedizin  
Zentralinstitut für Seelische Gesundheit  
Universität Heidelberg**

**J5**

**68159 Mannheim**

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Deutsches Register  
Klinischer Studien

German Clinical  
Trials Register

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Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

## 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.