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Predictors for successful treatment outcome in patients with comorbid attention-deficit /hyperactivity disorder (ADHD) and substance use disorder (SUD): an international observational cohort study

Submission date
20/12/2019

Recruitment status
No longer recruiting

Registration date
06/02/2020

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Patients with substance use disorder (SUD) are three to four times more likely to have attention deficit/hyperactivity disorder (ADHD) compared to the general population. Standard treatments for ADHD has not proven to be as effective in comorbid patients as in patients with ADHD only. There is currently a lack of knowledge of how to best treat patients with comorbid ADHD-SUD.

The purpose of this study is to gain more knowledge regarding treatments provided, and treatment outcome for patients with ADHD and substance use disorder. The study is observational and the aim is to describe the natural course of the disorders, and to identify factors that might predict a successful treatment result, i.e. retention to treatment and reduction in ADHD and SUD symptoms.

Who can participate?
This study will invite 600 adult (≥18 years) treatment seeking patients with comorbid ADHD and SUD.

What does the study involve?
Participants will be asked for informed consent to provide self-reported data at the start of treatment, and after 3 and 9 months, respectively. Data from the patient files will be collected, e g to confirm whether a patient is still in treatment or not.

What are the possible benefits and risks of participating?
This a naturalistic study, observational study and participation does not affect the participants treatment in any way. Participants will not receive any compensation.

Where is the study run from?
The study is a multicentre international study from different countries in Europe, USA and Australia.

When is the study starting and how long is it expected to run for?
The study is is anticipated to go on between June 2017 and May 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
INCAS: International Naturalistic Cohort Study of ADHD and Substance Use Disorders Study

Acronym

INCAS

Study objectives
The primary aim of the study is descriptive rather than hypothesis driven: To investigate the treatment modalitites provided to individuals with comorbid ADHD/SUD who are currently in treatment at SUD treatment services, and to identify predictors for successful treatment outcomes, as measured by retention, substance use and ADHD symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/06/2017, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: 2017/973-32

Study design
Naturalistic multicenter observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Attention deficit hyperactivity/impulsivity disorder with comorbid substance use disorder

Interventions
This study is non-interventional and investigates the treatment modalities provided to the study population at the participating treatment services.

This study will invite 600 treatment-seeking patients from different countries in Europe, USA and Australia to participate for 9 months. Participants will be asked for informed consent to provide self-reported data at the start of treatment, and after 3 and 9 months, respectively. Data from the patient files will be collected, e.g. to confirm whether a patient is still in treatment or not. This a naturalistic study, observational study and participation does not affect the participants' treatment in any way.

Intervention Type
Other

Primary outcome(s)
1. Retention to treatment, defined as time to drop-out (last contact between patient and treatment center)
2. ADHD symptoms measured using the Adult ADHD Self-Report Scale (ASRS) at 3 months follow-up
3. Number of days with heavy alcohol use or days with illicit drug use during the last 30 days, measured using the Time-Line Follow-Back instrument at 3 months follow-up

Key secondary outcome(s))

1. ADHD symptoms measured using the adult ASRS at 9 months follow-up
2. Substance use measured with TLFB, defined as the number of days with heavy alcohol use or days with illicit drug use the last 30 days at 9 months follow-up.
3. ADHD symptoms according to the Expanded Adult ADHD Self-Report Scale at 3 and 9 months follow-up, respectively
4. Employment measured using questionnaire and patient files at baseline, 3 months and 9 months
5. Number of accidents as reported by the participant using questionnaire and patient files at baseline, 3 months and 9 months
6. Days with any alcohol use during the last 30 days measured using Timeline Follow-Back interview at baseline, 3 months and 9 months follow-up

Completion date
31/05/2022

Eligibility

Key inclusion criteria
1. Men and women ≥18 years of age seeking treatment for SUD at any of the participating sites
2. ADHD diagnosis according to DSM-5
3. SUD diagnosis (DSM-5 moderate to severe, ICD-10 dependence)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
578

Key exclusion criteria
There are no formal exclusion criteria except incapability to complete the assessments

Date of first enrolment
01/07/2017

Date of final enrolment
30/06/2021

Locations

Countries of recruitment
Australia

Belgium

France

Germany

Hungary

Netherlands

Spain

Sweden

Switzerland

United States of America

Study participating centre
Stockholm Centre for Dependency Disorders
Friskvårdsvägen 4, plan 2, St:Göran
Stockholm
Sweden
112 81

Study participating centre
Multiversum Boechout, Cadenza 2
Provinciesteenweg 408
Antwerpen
Belgium
2530 Boechout

Study participating centre
Nyírő Gyula National Institute of Psychiatry and Addictions
Jász street 14
Budapest
Hungary
1135

Study participating centre
De Hoop ggz
Provincialeweg 70
Dordrecht
Netherlands
3329

Study participating centre
UPD Bern
Bolligenstrasse 111
3000 Bern 60
Switzerland
3000 Bern 60

Study participating centre
Novadik-Kentron
Hogedwarsstraat 3
Vught
Netherlands
5261 LX

Study participating centre
Tactus verslavingszorg
Linie 612
Apeldoorn,
Netherlands
7325 DZ

Sponsor information

Organisation
Beroendecentrum Stockholm

ROR
https://ror.org/04g380834

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to regional data protection regulations.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/12/2024	17/01/2025	Yes	No
Protocol article		23/09/2022	29/09/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			11/05/2021	No	No