Objectifying the day-time response variation of (lis)dexamphetamine in adults with ADHD.

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The objective is to compare the pharmacodynamic profile of dex and lisdex in adult patients with ADHD and determine whether the day-time response variation in ADHD symptomatology depends on the type of amphetamine and it's pharmacokinetics.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Developmental disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON50997

Source
ToetsingOnline

Brief title
day-time response variation of (lis)dexamphetamine

Condition

- Developmental disorders NEC

Synonym
ADHD, Attention deficit hyperactivity disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ADHDcentraal

Intervention

Keyword: Dexamphetamine, Lisdexamphetamine, Pharmacodynamics, Pharmacokinetics, Quantified behavioral test

Outcome measures

Primary outcome

The objective is to compare the pharmacodynamic profile of dex and lisdex in

adult patients with ADHD and determine whether the day-time response variation

in ADHD symptomatology depends on the type of amphetamine and it's

pharmacokinetics.

The PD profiles will be compared to the PK profiles to objectify the day-time

response variation for both types of amphetamines.

The main study parameters will include:

1. Comparison of the PK/PD profile

Secondary outcome

The secondary study parameters will include:

1. Compare the AUC (T0-12) of dex and lisdex

2. The effects at Cmax and Tmax will be compared

i. QbTest

ii. The Drug Effects Questionnaire (DEQ)

iii. Bond-Lader Visual Analog Scale (BL-VAS)

iv. QbTest performance questionnaire

v. Cardiovascular response

other study parameters:

Other study parameters that will be recorded include the following baseline

values that are considered to influence the primary and secondary endpoints:

1. The Leeds Sleep Evaluation Questionnaire (LSEQ)

2. Comparison of baseline characteristics

Study description

Background summary

In the Netherlands, two types of amphetamines are available for the treatment of adults with ADHD: dexamphetamine sulfate (dex [Tentin]) and Lisdexamphetamine dimesylate (lisdex [Elvanse]). Lisdex is promoted by the manufacturer as a long-acting preparation with a controlled release profile and thus an extended duration of action compared to dex, however, the scientific evidence about the PK/PD profile of lisdex is sparse. Additionally, there are insufficient head-to-head comparisons between dex and lisdex where an objective measurement for the symptom amelioration of ADHD has been used and compared to the plasma concentrations. We hypothesize that two-times daily dex is more effective in suppressing ADHD symptomatology than once daily lisdex.

Study objective

The objective is to compare the pharmacodynamic profile of dex and lisdex in adult patients with ADHD and determine whether the day-time response variation in ADHD symptomatology depends on the type of amphetamine and it's pharmacokinetics.

Study design

An observational study where sixteen participants will be observed for two days for the PK/PD profiles of lisdex and dex. Lisdex will be bioequivalently dosed; lisdex once a day and dex two times a day with an interval of 4 hours (TAU) The participants will be observed for approximately 14 hours each day. Blood samples, the Quantified behavior Test (QbTest), physical measurements and questionnaires for drug effects will be taken 6 times at; 0, 2; 4; 6; 9; 12.

Study burden and risks

There are no specific benefits for the study participants. The burden of

participating in this study include two extra visits to the outpatient clinic, during each visit the study participant has to fill out some questionnaires, undergo six QbTests and bloodtests. In our opinion the burden for each study participant is considered minor and the risk very low. The therapy given during the study is according to the TAU, which is based on the guidelines of the Dutch association of psychiatry (NVvP) for the treatment of ADHD in adults. The participants will be sampled for blood 12 times (2ml). We believe that this risk is acceptable in relation to the possible benefits that may be gained from this study, i.e. improved pharmacotherapy treatment guidelines for adult patients with ADHD.

Contacts

Public
Academisch Medisch Centrum

Meidreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meidreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participant is aged between 18 * 60 years at time of diagnosis
Participant is diagnosed with ADHD according to the DSM 5 criteria
Participant started pharmacotherapy treatment with dex or lisdex but no real preference for the type of amphetamine exists according to the practitioner
Participant is able to provide written informed consent
Participant is able and willing to comply with the study protocol

Exclusion criteria

No diagnosis for ADHD
Currently other psychopharmacotherapy treatment than dex or lisdex
Currently other psychopharmacotherapy parallel to dex or lisdex

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-07-2021
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	14-06-2021
Application type:	First submission

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL77195.018.21
Other	volgt (NCT)