Consortium for the Lifespan Examination of ADHD Registry (CLEAR) Study: An International, Longitudinal, Observational Study of Individuals with Attention-Deficit/Hyperactivity Disorder (ADHD)

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON34203

Source
ToetsingOnline

Brief title
CLEAR

Condition

- Cognitive and attention disorders and disturbances

Synonym
hyperactivity, hyperkinetic syndrome

Research involving

Human

Sponsors and support

Primary sponsor: Shire
Source(s) of monetary or material Support: Farmaceutische industrie.

Intervention

Keyword: ADHD

Outcome measures

Primary outcome

Multiple study questions, rather than hypotheses, will be addressed over the

course of the study.

Secondary outcome

Multiple study questions, rather than hypotheses, will be addressed over the

course of the study.

Study description

Background summary

Naturalistic data regarding the course and burden of ADHD, collected in a global longitudinal registry is essential
to inform clinicians, health care regulatory agencies, health care payers, and patients about the disease. The
collection of observational data in a scientifically designed registry allows for multiple real-world comparison of
clinical, patient-reported process of care and cost outcomes without many of the constraints of clinical trial
designs. As a result, registry data is more representative of the target patient population than data collected in
controlled study environments and is often more helpful in understanding the life course and longitudinal impacts
of a disease.

Study objective

The overall objectives of CLEAR are to improve our global understanding of the longitudinal impact of
attention-deficit/hyperactivity disorder (ADHD) and contribute to the body of scientific evidence regarding the
treatment and evolution of ADHD over the life course by addressing critical gaps in our current understanding
with prospective data from a scientifically rigorous study. Treatment patterns and outcomes, burden of illness
(patient rated health outcomes), and costs associated with ADHD and its treatment will be examined.
Multiple study questions, rather than hypotheses, will be addressed over the course of the study. Genetic factors
involved in ADHD will also be examined in subsequent years as appropriate scientific questions are formulated.
The 10 study questions which will be initially addressed are the following:
1. What is the course of ADHD across the lifespan for:
a. Treatment outcomes (patient and physician/clinician reported)?
b. Attitudes about ADHD/treatment?
c. Treatment patterns?
d. ADHD status (severity, symptoms, impairments, co-morbidities)?

2. What is the impact of diagnosis and/or treatment (type of treatment, length of treatment) in childhood for
adult ADHD parameters?

3. What are the consequences of treatment (type and length of treatment) in ADHD?
a. Patient-reported treatment outcomes (Quality of Life [QoL], disability, etc.)
b. ADHD status (severity, symptoms, impairments, co-morbidities)?

4. What are the short- and long-term treatment patterns (eg, switching, on/off pattern, etc.) for ADHD?
a. How can they be classified?
b. What are the factors (both patient and disease) which explain these patterns (eg, reasons for switching,
non treatment)?

5. What are the differences between ADHD treatments?
a. Compliance (reasons for, rates)
b. Patient-reported treatment outcomes (QoL, disability)
c. Patient characteristics
d. ADHD status (severity, symptoms, impairments, co-morbidities)?

6. What is the relationship between disease severity and:
a. Treatment outcomes (patient and physician/clinician reported)?
b. Treatment patterns?
c. Treatment type?

d. Patient characteristics?

7. Is there increased risk of substance abuse, disruptive behavior, or intentional self harm that can be attributed specifically to the disease itself after adjusting for other relevant factors (co-morbid conditions, treatments) in ADHD? What are the patient factors that increase or decrease these risks (eg, pharmacotherapy, misdiagnosis of ADHD, history of prior substance abuse, etc.)?

8. What are the costs associated with ADHD?
a. From the payer perspective (direct medical, social)?
b. From the patient perspective?
c. Is there a cost offset for treatment?

9. How do physicians/clinicians and countries differ regarding:
a. How patient is identified and diagnosed?
b. Reasons for treatment vs. non-treatment?
c. Time from diagnosis to treatment; reasons for delay of treatment?
d. Types of treatment and reasons for choice?
e. Assessments used to track patient status?
f. Treatment differences for newly diagnosed vs. ongoing treatment?
g. Perspective on abuse potential of treatments?

10. What is the relationship between ADHD status (symptom severity) and costs? Does a decrease in symptoms translate into a decrease in costs?

Study design

CLEAR is a prospective, observational registry of persons with ADHD. Physicians and other healthcare clinicians appropriately trained and licensed to conduct activities related to the management and treatment of ADHD, including protocol-required assessment measures, will identify/enroll previously and newly diagnosed ADHD patients. There will be at least 3 types of sites across 5 countries for the registry: primary care practices, psychiatry practices, and educational institutions* health care centers. Additionally, other appropriate institutions (as applicable per country) may be considered for inclusion.

To better understand genetic factors involved in ADHD, voluntary saliva samples may be collected in order to research the association of specific genes and ADHD. Samples may be collected upon screening/enrollment or at a later regular clinic visit. After the Screening/Enrollment Visit, patient data will be collected independently of physician/clinician visits by the Contract Research Organization (CRO) using either a web-based interface or computer assisted telephone interview (CATI). Patient data collected by the CRO will only be shared with their physician/clinician with patient consent, with the exception

of notification of at-risk suicidal behavior/ideation as defined in the protocol. Physician/clinician-reported data will be collected through medical record abstraction to a web-based interface. Sites will be monitored for data quality assurance and adverse drug reactions (ADRs) for Shire marketed products and prescription ADHD products (ie, labeled for use in ADHD) will be captured.

Study burden and risks

See also section E9 and E9a of the ABR form.

Contacts

Public
Shire

725 Chesterbrook Boulevard
19087 Wayne Pennsylvania
USA
Scientific
Shire

725 Chesterbrook Boulevard
19087 Wayne Pennsylvania
USA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients meeting all of the criteria listed below at the time of consent may be included in the study:
1. Documented diagnosis of ADHD by a physician/clinician.
2. Age 18 years or older.
3. Read, comprehend, and speak the native language of the country in which they reside.
4. An understanding, ability, and willingness to participate in the study and comply with the requirements of the
protocol.
5. Ability to provide written, signed, and dated (personally) informed consent to participate in the study.

Exclusion criteria

Patients are excluded from the study if any of the following criteria are met at screening/enrollment:
1. Life expectancy less than 12 months.
2. Currently enrolled in an ADHD clinical trial.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	250
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-07-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-10-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	17-08-2011
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL32868.028.10