Attentin® in Children and Adolescents With ADHD - A Non-interventional Study (Attention)

This study is currently recruiting participants. (see Contacts and Locations)

Verified June 2016 by Medice Arzneimittel Pütter GmbH & Co KG

Sponsor:
Medice Arzneimittel Pütter GmbH & Co KG
Collaborator:
University Hospital, Essen

Information provided by (Responsible Party):
Medice Arzneimittel Pütter GmbH & Co KG

ClinicalTrials.gov Identifier:
NCT02801604

First received: June 2, 2016
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Purpose

The practicality of most ADHD medications is not or only moderately examined under long term routine conditions. Therefore, in this multi-centre, multi-national prospective non-interventional study, a recommended follow-up time of 12 months will investigate the course of the therapy in children and adolescents with ADHD with prior MPH treatment and their medication change to dexamfetamine in several European countries under daily routine.

It consists of a baseline visit under MPH or another ADHD drug therapy, a change to dexamfetamine, the prospective description of the titration phase and a 12 month maintenance phase. Data on the use of dexamfetamine in routine clinical practice will be collected to describe how dexamfetamine is prescribed, titrated and used in the population of ADHD patients and how these factors influence the general intensity of ADHD and safety events. This study will collect real world data of dexamfetamine and compare descriptively the general intensity of ADHD according to ADHD classification and the impairment due to ADHD under therapy with dexamfetamine to the general intensity of ADHD according to ADHD classification and the impairment due to ADHD under the prior therapy with MPH. Furthermore the utilization of dexamfetamine will be assessed with regards to treatment persistence, compliance, proportion of patients discontinuing treatment and reason for discontinuation. Due to the fact that patients will be treated according to local medical practice it is possible that medication will be changed during the observation period.
Study Type: Observational

Study Design: Observational Model: Case-Only
Time Perspective: Prospective

Official Title: Attentin® in Children and Adolescents With ADHD - A Non-interventional Study

Further study details as provided by Medice Arzneimittel Pütter GmbH & Co KG:

Primary Outcome Measures:
- ADHD classification [Time Frame: baseline until 1st follow-up visit after 6 months]
  [Designated as safety issue: No]
  change from baseline under MPH therapy to the 1st follow-up visit after 6 months under dexamfetamine, assessment by ADHD Rating Scale IV

Secondary Outcome Measures:
- ADHD classification subgroup: Age [Time Frame: baseline until 1st follow-up visit after 6 months]
  [Designated as safety issue: No]
  change from baseline to 1st follow-up in subgroup of age in years

- ADHD classification subgroup: Dose under MPH therapy [Time Frame: baseline until 1st follow-up visit after 6 months]
  [Designated as safety issue: No]
  change from baseline to 1st follow-up in subgroup of MPH dose in mg

- ADHD classification subgroup: Dose under dexamfetamine therapy [Time Frame: baseline until 1st follow-up visit after 6 months]
  [Designated as safety issue: No]
  change from baseline to 1st follow-up in subgroup of dexamfetamine dose in mg

- ADHD classification subgroup: Baseline ADHD classification [Time Frame: baseline until 1st follow-up visit after 6 months]
  [Designated as safety issue: No]
  change from baseline to 1st follow-up in subgroup baseline ADHD classification, assessment by ADHD Rating Scale IV

- Dose-response relationship between dose under dexamfetamine and ADHD classification at 1st follow-up [Time Frame: at 1st follow-up visit, 6 months after baseline]
  [Designated as safety issue: No]

- ADHD classification change from baseline to titration and from baseline to 2nd follow-up after 1 year under dexamfetamine [Time Frame: baseline until 2nd follow-up visit after 1 year of examination]
  [Designated as safety issue: No]
Assessment by ADHD Rating Scale IV

- Subscales hyperactivity/impulsivity [Time Frame: baseline until 2nd follow-up visit after 1 year of examination] [Designated as safety issue: No]

Assessment by ADHD Rating Scale IV

- Subscales inattention [Time Frame: baseline until 2nd follow-up visit after 1 year of examination] [Designated as safety issue: No]

Response rate, relative reduction in ADHD classification from baseline to 1st follow-up of 30% or more [Time Frame: baseline until 1st follow-up visit after 6 months] [Designated as safety issue: No]

Overall impairment of the patient's everyday life and disability due to ADHD concerning home life [Time Frame: baseline until 2nd follow-up visit after 1 year of examination] [Designated as safety issue: No]

Assessment for home life

Overall impairment of the patient's everyday life and disability due to ADHD concerning friendships [Time Frame: baseline until 2nd follow-up visit after 1 year of examination] [Designated as safety issue: No]

Assessment for friendships

Overall impairment of the patient's everyday life and disability due to ADHD concerning classroom learning [Time Frame: baseline until 2nd follow-up visit after 1 year of examination] [Designated as safety issue: No]

Assessment for classroom learning

Overall impairment of the patient's everyday life and disability due to ADHD concerning leisure activities [Time Frame: baseline until 2nd follow-up visit after 1 year of examination] [Designated as safety issue: No]

Assessment for leisure activities

Compliance of last MPH intake [Time Frame: baseline] [Designated as safety issue: No] estimated in per cent

Compliance of last ADHD medication intake (other than MPH) [Time Frame: baseline] [Designated as safety issue: No] estimated in per cent

Compliance of dexamfetamine intake [Time Frame: titration until 2nd follow-up visit after 1 year of examination] [Designated as safety issue: No] estimated in per cent
- Adverse Drug Reactions under ADHD medication, assessment of blood pressure in mmHg [ Time Frame: baseline until 2nd follow-up visit after 1 year of examination ] [ Designated as safety issue: Yes ]
  Assessment of vital parameter: blood pressure in mmHg

- Adverse Drug Reactions under ADHD medication, assessment of pulse in beats/min [ Time Frame: baseline until 2nd follow-up visit after 1 year of examination ] [ Designated as safety issue: Yes ]
  Assessment of vital parameter: pulse in beats/min

- Adverse Drug Reactions under ADHD medication, assessment of weight in kg [ Time Frame: baseline until 2nd follow-up visit after 1 year of examination ] [ Designated as safety issue: Yes ]
  Assessment of vital parameter: weight in kg

- Adverse Drug Reactions under ADHD medication, assessment of height in cm [ Time Frame: baseline until 2nd follow-up visit after 1 year of examination ] [ Designated as safety issue: Yes ]
  Assessment of vital parameter: height in cm

Estimated Enrollment: 500

Study Start Date: June 2016

Estimated Study Completion Date: March 2018

Estimated Primary Completion Date: November 2017 (Final data collection date for primary outcome measure)

Eligibility

Ages Eligible for Study: 6 Years to 215 Months

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Sampling Method: Non-Probability Sample

Study Population

Children and adolescents (Age ≥ 6 to 17.11 years) with ADHD, who were treated with methylphenidate (MPH) in the past and, when response to previous MPH treatment is considered clinically inadequate, will be treated with dexamfetamine in this non-interventional study. ADHD was classified according to a classification system of the DSM or ICD and the patient should have no contraindication against dexamfetamine.

Criteria

Inclusion Criteria:

- Age ≥ 6 to 17.11 years
- Current MPH therapy insufficient
- ADHD was classified according to a validated classification system (e.g. DSM or ICD-10)
- No contraindication against dexamfetamine
Contraindication against dexamfetamine

Contacts and Locations
Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02801604

Contacts
Contact: Oliver Dangel, Dr. +49 2371 937 ext 0 ATTENTION-NIS@medice.de
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Locations

Germany

Child and Adolescent Psychiatry, University of Medicine Recruiting
Mainz, Germany
Contact: Michael Huss, Prof. Dr.

Sponsors and Collaborators
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Investigators
Principal Investigator: Michael Huss, Prof. Dr. Child and Adolescent Psychiatry, University of Medicine, Mainz, Germany

More Information

Responsible Party: Medice Arzneimittel Pütter GmbH & Co KG
ClinicalTrials.gov Identifier: NCT02801604 History of Changes
Other Study ID Numbers: Attention
Study First Received: June 2, 2016
Last Updated: June 13, 2016
Health Authority: Germany: Federal Institute for Drugs and Medical Devices
Germany: Ethics Commission
Germany: GKV Spitzenverband Bund der Krankenkassen
Germany: Kassenärztliche Bundesvereinigung
Germany: Verband der Privaten Krankenversicherung
Sweden: Regional Ethical Review Board

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity
Attention Deficit and Disruptive Behavior Disorders
Mental Disorders
Neurodevelopmental Disorders

ClinicalTrials.gov processed this record on June 15, 2016