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Effect of methylphenidate formulation on attention deficit hyperactivity disorder (ADHD)-patients' adherence to medical treatment. A comparison of Medikinet retard® (extended-release [ER]) once daily and Medikinet® (immediate-release [IR]) twice daily in children and adolescents diagnosed with ADHD

Submission date
05/03/2009

Registration date
30/04/2009

Last Edited
19/02/2019

Recruitment status
No longer recruiting

Overall study status
Stopped

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00852059

Protocol serial number
2.0

Study information

Scientific Title
Effect of methylphenidate formulation on attention deficit hyperactivity disorder (ADHD)-patients' adherence to medical treatment. A comparison of Medikinet retard® (extended-release [ER]) once daily and Medikinet® (immediate-release [IR]) twice daily in children and adolescents diagnosed with ADHD: a prospective open-label randomised active-controlled multi-centre trial

Acronym
ASTA (Adherence to stimulant treatment in ADHD-patients)

Study objectives
It is supposed that extended-release (ER) formulations increase treatment adherence, because children and adolescents cannot forget a second or third dose and are at lower risk to stigmatisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Landesärztekammer Rheinlandpfalz. Protocol Version 2.0 and Amendment 1.0 approved on 09/02/2009 (ref: 837.224.08[6221]).

Study design
Prospective open-label randomised active-controlled multi-centre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Children and adolescents diagnosed with attention deficit hyperactivity disorder (ADHD)

Interventions
Before the clinical intervention, patients are observed for 4 weeks (baseline). Randomisation (ratio 1:1) to methylphenidate extended release or immediate release twice daily.

Test product: Medikinet retard® (oral)
Reference therapy: Medikinet® (oral)

Dosage is individualised according to body weight and the dosage previously given by the paediatrician. The total duration of the clinical intervention is 100 +/- 5 days.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Medikinet retard® (methylphenidate), Medikinet® (methylphenidate)

Primary outcome(s)
Non-adherence assessed by the number of non-adherent days during the clinical trial of 100 days using the Medication Event Monitoring System (MEMS).

Key secondary outcome(s))
1. To measure the number of non-adherent days during the clinical trial assessed by MEMS at Visit 1, Visit 2 and Visit 3
2. To measure the number of non-adherent days during the clinical trial assessed by pill count at Visit 1, Visit 2 and Visit 3
3. To measure the time interval until a total number of 30 days of non-adherence (days with deviant intake behaviour) is reached cumulatively during the clinical trial, measured by MEMS at Visit 1, Visit 2 and Visit 3
4. To measure the quality of life during the clinical trial measured by Child Health Illness Profile Child Edition (CHIP-CE) Score at Visit 1, Visit 2 and Visit 3
5. To measure the efficacy of stimulant treatment during the clinical trial measured by ADHD-Rating Scale- Parent Version Sum Score at Visit 1, Visit 2 and Visit 3
6. To measure the adverse events during the clinical trial measured at Visit 1, Visit 2 and Visit 3

Timepoints of assessment:
Screening: within 1 week before the start of the baseline-observation
Run-In-Visit: start of the baseline-observation, which takes place the four weeks before the clinical observation
Visit 1: start of the clinical trial
Visit 2: 50 +/- 5 days after Visit 1
Visit 3: 100 +/- 5 days after Visit 1; end of the clinical intervention

Completion date
15/08/2010

Eligibility

Key inclusion criteria
Subjects meeting all of the following criteria are considered for enrolment into the trial:
1. Written informed consent (separately for children aged 6-11 years and 12-17 years)
2. Children and adolescents of both sexes aged 6 - 17 years
3. Confirmed diagnosis of ADHD by semi structured-clinical interview (K-SADS)
4. The ADHD Rating Scale-IV (ADHDRS-IV) Parent Version (18-Item-Scale) raw score >=1.5 SD above norm under non-medicated conditions (either drug holiday or prior to medication within

the past 6 months)
5. Effective treatment with a stable dose of methylphenidate for at least one month (max. 60 mg /day) proved by a 25% symptom reduction in ADHD Rating Scale (ADHD-RS) under medication, compared to retrospective ADHD-RS without medication within the past 6 months
6. Acceptance and capability to swallow capsules of product size, proved by an equally sized placebo provided by Medice®
7. Sufficient knowledge of the German language
8. Adequate contraception in case of sexual activity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
17 years

Sex
All

Key exclusion criteria
Subjects fulfilling any of the following criteria will not be enrolled into the trial:
1. Contraindications against methylphenidate
1.1. Allergy or hypersensitivity against methylphenidate or methylphenidate derivate or any other ingredient of the product
1.2. Severe anxiety disorder, high tenseness or arousal, depression, psychosis
1.3. Hyperthyroidism
1.4. Glaucoma
1.5. Thyreotoxicosis
1.6. Severe angina pectoris
1.7. Cardiac arrhythmia
1.8. Severe hypertension
1.9. Heart insufficiency
1.10. Myocardial infarction
1.11. Known substance abuse or alcoholism
1.12. Intake of Monoamine oxidase (MAO) inhibitor at the same time or during the last 14 days
1.13. Tic-disorder or tic disorder in family history
1.14. Pregnancy, lactation
1.15. Marked gastric anacidity
2. Previous stable methylphenidate intake more than twice daily
3. All severe psychiatric disorders except oppositional defiant disorder (ODD) or conduct disorder. In order to reflect the usual co-morbid spectrum of ADHD, mild or moderate anxiety or depressive disorders are accepted in the study.
4. All severe somatic diseases as assessed by the baseline examination or medical history

(including life-time history of epileptic disorders)
5. Pathological results for vital signs, blood pressure and pulse
6. Reported pathological results for
6.1. Electrocardiogram (ECG) during the last 12 months
6.2. Differential blood count and hepatic metabolism during the last 6 months
7. Indication for hospitalization
8. Suicidality (assessed by Montgomery-Asberg Depression Rating Scale (MADRS) Item 10, Score >=3)
9. IQ <70 (clinically assessed)
10. Any psychotropic co-medication
11. Detention in an institution on official or judicial ruling
12. Unwillingness to transmit pseudonym data according to German regulations
13. Simultaneous participation in another clinical trial according to German Drug Law (AMG)

Date of first enrolment
15/03/2009

Date of final enrolment
15/08/2010

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsmedizin der Johannes Gutenberg-Universität Mainz
Mainz
Germany
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Sponsor information

Organisation
Johannes Gutenberg University of Mainz (Germany)

ROR
https://ror.org/023b0x485

Funder(s)

Funder type
Industry

Funder Name
Medice Arzneimittel Pütter GmbH & Co KG (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes