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The effects of Concerta® on the brain structures of children with attention deficit hyperactivity disorder, measured by optimised Voxel-Based Morphometry (VBM) and Tract-Based Spatial Statistics (TBSS) of Diffusion Tensor Imaging (DTI).

Submission date
14/04/2008

Registration date
22/04/2008

Last Edited
10/12/2009

Recruitment status
No longer recruiting

Overall study status
Completed

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2005-0161

Study information

Scientific Title

Acronym
COSA

Study objectives
1. Methyphenidate (Concerta®) will change the brain structures of subjects with attention-deficit hyperactivity disorder (ADHD)
2. Structural changes of brain will be correlated with the changes of symptoms severity after treatment

Please note that as of 02/09/09 the the imaging techniques used in this trial have been updated. The original techniques which were to be used are three-dimensional magnetic resonance (3D-MR) volumetry and diffusion-tensor imaging (DTI). The trial name and primary outcome field have been updated accordingly. Please also note that the target of 30 participants was expanded due to a high dropout rate during follow up and the anticipated end date has been changed from 31/12/2008 to 31/12/2012.

Please note that as of 10/12/09 the target number of participants has been changed from 120 to 80.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Institutional Review Board (IRB) of the Asan Medical Centre (AMC) on the 22nd August 2005.

Study design
Prospective open-label controlled study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Attention deficit hyperactivity disorder (ADHD)

Interventions
Day 0: Concerta® 18 mg
Week 2: Concerta® 36 mg
Week 4: Concerta® 54 mg

Dosage can be adjusted according to clinical symptoms and adverse effects. Patients will be treated for one year, and a patient follow-up will be performed for one year.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Methyphenidate (Concerta®)

Primary outcome measure
Current information as of 02/09/09:
Image analysis data including cortical thickness, shape analysis, and diffusion tensor image, measured at baseline, 2 months, 1 years, 2 years and 3 years

Initial information at time of registration:
Cortical thickness changes measured by 3D-MR, measured at baseline, eight weeks, and one year.

Secondary outcome measures
1. ADHD rating scale by investigator, measured at baseline, eight weeks, and one year
2. Clinical Global Impression - Improvement/Severity (CGI-I/S) scale, measured at every visit
3. Junior Temperament and Character Inventory, measured at baseline, eight weeks, and one year
4. Computerised neurocognitive function tests, measured at baseline, eight weeks, and one year

Overall study start date
23/08/2005

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Aged 6 - 12 years old, male only
2. ADHD diagnosed by the Kiddie Schedule for Affective Disorders and Schizophrenia - Present

and Lifetime Version (KSADS-PL)
3. Right-handedness
4. ADHD rating scale score greater than 24
5. Healthy control group (age-matched boys) (added 02/09/09)

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Male

Target number of participants
80 subjects (ADHD 50 subjects; control 30 subjects) (added 10/12/09)

Key exclusion criteria
1. Intelligence quotient (IQ) less than or equal to 70 measured by the Wechsler Intelligence Scale for Children - Revised (WISC-R)
2. Neurological diseases such as cerebral palsy, seizure disorder, head trauma etc.
3. Autistic spectrum disorder
4. History or current diagnosis of tic disorder, schizophrenia, bipolar disorder, major depression, anxiety disorder and other psychosis
5. History of psychotropic medication usage
6. Contra-indication of magnetic resonance imaging (MRI) scanning (e.g., pacemaker insertion)

Date of first enrolment
23/08/2005

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Korea, South

Study participating centre
388-1 Pungnap-2 dong
Seoul
Korea, South
138-736

Sponsor information

Organisation
Janssen Korea Ltd (South Korea)

Sponsor details
12th Floor Sungwon Building
141 Samsung-Dong
Gangnam-ku
Seoul
Korea, South
135-090

Sponsor type
Industry

ROR
https://ror.org/04yzcpd71

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Janssen Korea Ltd (South Korea)

Funder Name
Asan Medical Centre (South Korea)

Funder Name
National Research Foundation of Korea (South Korea)

Alternative Name(s)
, National Research Foundation (South Korea), NRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Korea, South

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration