# 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

**Contact name**
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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)

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.

## Key secondary outcome(s))

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

## 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

## Healthy volunteers allowed

No

## Age group

Child

## Lower age limit

6 years

## Upper age limit

12 years

**Sex**
Male

**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)

**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

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration