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N-of-1 trials of stimulants versus placebo and each other for Attention Deficit Hyperactivity Disorder in children

Submission date	Recruitment status
04/08/2007	No longer recruiting
Registration date	**Overall study status**
16/08/2007	Completed
Last Edited	**Condition category**
21/05/2019	Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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The University of Queensland
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4006

Additional identifiers

Protocol serial number
ADHDAHMACGEN version 2; Also registered in Australian Clinical Trials Registry: ACTRN12605000507684

Study information

Scientific Title
N-of-1 trials of stimulants versus placebo and each other for Attention Deficit Hyperactivity Disorder in children

Acronym
ADHDIMET

Study objectives
1. N-of-1 trials will improve therapeutic decision making about Attention Deficit Hyperactivity Disorder (ADHD) medications, by educating the doctor and the patient in the use of N-of-1 trial methodology for objective individual patient decision making
2. N-of-1 trials will be able to evaluate individual patient responses to stimulants in terms of relief of ADHD symptoms, and immediate side-effect profile

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Queensland Medical Research Ethics Committee and the Mater Misericordiae Hospital Medical Research Ethics Committee approved the study.

Primary study design
Interventional

Study design
This N-of-1 trial is a randomised, double-blind, cross-over comparison of stimulants (methylphenidate or dexamphetamine) and placebo within an individual patient.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Attention Deficit Hyperactivity Disorder

Interventions
1. Stimulant versus placebo
2. Stimulant versus stimulant

The stimulants being tested will be dexamphetamine and methylphenidate, compared to placebo and each other. The dose will be individualised by the child's doctor to the optimum dose without side effects, and will be taken orally at morning and lunchtime. There are two types of trials: treatments will take place in three day or one week periods; each pair of periods will be repeated three times (total of 3 and 6 weeks respectively). Follow-up will be for one year.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Methylphenidate, dexamphetamine

Primary outcome(s)

1. Conners' Teacher and Parent self reported revised short form
2. Conners-Wells Adolescent Rating Scales

Outcomes will be measured at baseline and at the end of each treatment period.

Key secondary outcome(s)
No secondary outcome measures

Completion date
01/05/2005

Eligibility

Key inclusion criteria
1. Any school age patient with a clinical diagnosis of ADHD of at least a month's duration, in the opinion of the attending medical practitioner, who is stabilised on treatment with Ritalin
2. Patient, parent and doctor would like to use the n-of-1 trial methodology to see if the patient is a responder to methylphenidate or dexamphetamine

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
Not Specified

Total final enrolment
86

Key exclusion criteria
1. Advanced arteriosclerosis
2. Symptomatic cardiovascular disease
3. Moderate to severe hypertension
4. Hyperthyroidism
5. Phaeochromocytoma
6. Glaucoma
7. Agitated states
8. Anxiety
9. Motor tics
10. Tourette syndrome
11. Monoamine Oxidase Inhibitors (MAOIs) (+/- 14 days)
12. Idiosyncratic reaction to sympathomimetic amines
13. History of drug abuse

Date of first enrolment

01/12/1999

Date of final enrolment
01/05/2005

Locations

Countries of recruitment
Australia

Study participating centre
Division of General Practice
Brisbane
Australia
4006

Sponsor information

Organisation
The University of Queensland (Australia)

ROR
https://ror.org/00rqy9422

Funder(s)

Funder type
Government

Funder Name
General Practice Evaluation Program (GPEP) (Australia)

Funder Name
The Department of Health and Aged Care (Australia)

Funder Name
Queensland Medical Laboratory (Australia)

Funder Name
Mater Misericordiae Health Services (Brisbane, Australia)

Funder Name
The Royal Australian College of General Practitioners (Australia)

Funder Name
National Health and Medical Research Council (Australia) - medical postgraduate research scholarship (ref: 210364)

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?
Results article	results	01/06/2006	21/05/2019	Yes	No