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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	[ ] Prospectively registered
04/08/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/05/2019	Mental and Behavioural Disorders	

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
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.

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.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/12/1999

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

Age group
Child

Sex
Not Specified

Target number of participants
100

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)

Sponsor details
St. Lucia 4029
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Sponsor type
University/education

Website
http://www.uq.edu.au/

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2006	21/05/2019	Yes	No