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Biphentin Effects in attention deficit hyperactivity disorder (ADHD) Drivers

Submission date	Recruitment status	[ ] Prospectively registered
13/07/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/08/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/08/2010	Mental and Behavioural Disorders	[ ] 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
022-014

Study information

Scientific Title

BiphentinEffects in attention deficit hyperactivity disorder (ADHD) Drivers: a randomised, placebo controlled, crossover study of multilayer-release (MLR) methylphenidate on driving performance in adult ADHD patients

Acronym
BEAD

Study objectives
When optimised on multilayer-release (MLR) methylphenidate, attention deficit hyperactivity disorder (ADHD) subjects will show improvements in driving performance and cognitive function compared to tests on placebo.

As of 13/08/2010 this record was updated to include an extended end date; the initial anticipated end date at the time of registration was 13/12/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. IRB Services initially approved on the 8th December 2008 (ref: 022-014)
2. University of Guelph Ethics Board initially approved on the 8th January 2009 (ref: 09OC028)

Added 13/08/2010:
Ethics approval for the lead centre was obtained from IRB Services, Aurora, ON on 23rd July 2009. All other participating centres obtained ethics approval before recruiting study participants.

Study design
Randomised placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Interventions
The study is to evaluate the effect of MLR methylphenidate through a 16-hour period on driving performance and cognitive function in adult patients with ADHD. Dosage will be 10, 15, 20, 30, 40, 50, 60, 70 or 80 mg once daily of Biphentin (oral). Duration of treatment will be for between

3 and 12 weeks, depending on the length of dose titration required and the scheduling of week-end driving laboratory simulations. The termination/follow-up visit is scheduled one week after the final driving simulator.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Multilayer-release (MLR) methylphenidate

Primary outcome measure
Hazard Response Time (HRT) scores from the Driving Simulator, obtained during the two driving simulator visits, which occur at 2 to 5 weeks following randomisation.

Secondary outcome measures
1. Driving simulator measures of:
1.1. Steering control (standard deviation of steering, driving off the road, and veering across the midline)
1.2. Braking (inappropriate braking while on the open road, missed stopped signals, and collisions)
1.3. Speed control (exceeding speed limit, standard deviation of speed, time at stop sign deciding when to turn left, and time to complete left turns)
1.4. Video analysis (number of non-driving glances away from the road, time spent distracted)
All obtained during the two driving simulator visits, which occur at 2 to 5 weeks following randomisation.
2. Stop task: Go Task (ms), Mean Delay (ms) and Stop Signal Reaction Time (ms), obtained during the two driving simulator visits, which occur at 2 to 5 weeks following randomisation
3. Behaviour Rating Inventory of Executive Function (BRIEF), conducted once the therapeutic dose of methylphenidate has been set (between 1 and 5 weeks following randomisation)
4. Multiple-Object Tracker Task, obtained during the two driving simulator visits, which occur at 2 to 5 weeks following randomisation
5. Attentional Network Task, obtained during the two driving simulator visits, which occur at 2 to 5 weeks following randomisation

Overall study start date
31/07/2009

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Male or non-pregnant, non-nursing female patients at the age of 18 years or greater with a valid driver's license and at least six months of driving experience with driving activity at least twice per week
2. Patients must have a childhood history consistent with ADHD and must meet the Diagnostic

and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria for ADHD, inattentive or combined based on clinician assessment using multiple informants and a structured interview
3. Patients must be being treated with methylphenidate at the time of study entry. Either long-acting or short-acting formulations of methylphenidate are valid for study inclusion. Both the investigator and patient must rate satisfaction with treatment as satisfied or greater using a four-point ordinal scale (0 = unsatisfied, 1 = somewhat satisfied, 2 = satisfied, 3 = very satisfied)
4. In the case of women of childbearing potential, demonstration of a negative blood or urine pregnancy test at study entry or within seven days prior to study entry, and the use of a reliable method of contraception such as oral contraceptive, two barrier methods, a barrier method plus a spermicidal agent, female surgical sterilisation or abstinence
5. Patients who are mentally and physically competent to provide informed consent, and who have signed a form indicating their informed consent
6. Patients who are able and willing to comply with the study protocol
7. Patients who can be contacted by telephone at times specified by the protocol and who are able to return to the hospital or clinic for protocol specified visits and evaluations, including two weekends at the University of Guelph for the Driving Simulator

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Patients with a true allergy to methylphenidate or amphetamines, history of serious adverse reactions to methylphenidate or be known to be non-responsive to methylphenidate treatment. Non-response is defined as methylphenidate use at various doses for a period of at least four weeks at each dose with little or no clinical benefit.
2. Patients with a history of seizures, strokes, epilepsy, migraine headaches, glaucoma, thyrotoxicosis, tachyarrhythmias or severe angina pectoris or have serious or unstable medical illness, such as asthma, diabetes or seizures
3. Patients with elevated blood pressure, defined as any values above 90 mmHg diastolic and 150 mmHg systolic
4. Patients with a high risk of experiencing Simulator Adaptation Syndrome (SAS: a.k.a. Simulator Sickness)
5. Patients who are currently receiving guanethidine, pressor agents, monoamine oxidase [MAO] inhibitors, coumarin anticoagulants, anticonvulsants (e.g. phenobarbitol, phenytoin, primidone), phenylbutazone, tricyclic antidepressants (imipramine, desipramine), selective serotonin reuptake inhibitors (SSRIs) or herbal remedies (e.g. Effalux, valerian or melatonin)
6. Patients with a history of disorders of the sensory organs, particularly deafness or profound mental retardation

7. Patients with a diagnosis of schizophrenia, schizoaffective disorder, primary affective disorder, schizotypal personality, major depression, bipolar disorder, generalized anxiety, substance abuse, borderline personality disorder, antisocial personality or another unstable psychiatric condition requiring treatment, as assessed by a structured interview
8. Patients who are currently receiving any investigational drug, or have received an investigational drug in the previous month
9. Patients who are currently known or suspected to be abusing drugs or alcohol

Date of first enrolment
31/07/2009

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Canada

Study participating centre
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Sponsor information

Organisation
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Sponsor type
Industry

Website
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ROR

https://ror.org/023sxys58

Funder(s)

Funder type
Industry

Funder Name
Purdue Pharma (Canada)

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