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Brahmi (Bacopa Monnieri Linn) in the treatment of dementia

Submission date	Recruitment status	[ ] Prospectively registered
04/09/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/09/2016	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/10/2016	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
People are living longer than ever before and the incidence of Alzheimer's disease (AD) and other age-related dementias continues to increase worldwide; no treatment is available to reverse or even at least to halt satisfactorily the underlying pathology of established AD. The objective/aim of the study was to determine whether an extract of Brahmi (Bacopa monnieri Linn) could be useful in different types of dementia. Brahmi (Bacopa monnieri Linn) is a herb used traditionally in India as a memory-enhancer. We studied its effect on human memory and forgetfulness in dementia of various grades - from mild to severe. There are reports of its efficacy in various publications: Many relate to its effect in animals, some to its effect in human beings too. One such study showed that it decreased the rate of forgetting newly acquired information in humans while the rate of learning remained unaffected. None of the reports specifically mentions its effect in dementias. We decided to conduct a pilot study, thus laying the framework for definitive studies.

Who can participate?
Patients with dementia over the age of 18.

What does the study involve?
All participants are given Brahmi (Himalaya) 250 mg to take twice a day for three months. Before starting treatment and then after three months, participants complete a number of questionnaires in order to find out how bad their AD is, and if they have experienced any falls.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their cognitive function, especially their memory. There is a small risk of experiencing bloating after taking Brahmi, but this is very mild.

Where is the study run from?
Ambalike Clinic (India)

When is study starting and how long is it expected to run for?
June 2015 to May 2016

Who is funding the study?
Ambalike Clinic (India)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P01/2015

Study information

Scientific Title
A pilot study on the effect of Brahmi (Bacopa Monnieri Linn) in various types and grades of dementia by comparing the effect of the drug on the participants using the Global Deterioration Scale

Acronym
BITOD

Study objectives
Primary hypothesis:
Brahmi is useful in the treatment of dementias and helps reduce Global Deterioration Scale (GDS) score within three months

Secondary hypothesis
Treatment with Brahmi will lead to a reduction in age-related falls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ambalike Clinic Institutional Ethics committee, 15/04/2015, ref: 01/2015

Study design
Interventional single-centre non-randomised single arm open-label trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Dementia

Interventions
Every patient is administered the extract of Brahmi (Himalaya) in the dose of 250 mg capsules twice daily orally for three months. The GDS was determined before the start of the treatment and again after three months. After the final evaluation at the end of three months no further follow ups are planned.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Brahmi (Bacopa Monnieri Linn)

Primary outcome measure
Alzheimer's progression is measured using the Global Deterioration Scale (GDS) at baseline and 3 months.

Secondary outcome measures
Age-related falls are measured through self-reporting by patients and/or their attendants at baseline, 1 and 3 months.

Overall study start date
01/06/2015

Completion date
31/05/2016

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Diagnosis of dementia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
1. History of Intolerance or allergy to Brahmi
2. Type 1 Diabetes Mellitus
3. Pregnancy

Date of first enrolment
01/06/2015

Date of final enrolment
10/02/2016

Locations

Countries of recruitment
India

Study participating centre
Ambalike Clinic
Bengali Tola, Laheriasarai
Darbhanga
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Sponsor information

Organisation
Ambalike Clinic

Sponsor details
Bengali Tol
Laheriasarai
Darbhanga
India
846001

Sponsor type
Not defined

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ambalike Clinic

Results and Publications

Publication and dissemination plan
Planned publication of study results in a reputable journal by the end of 2016.

Intention to publish date
31/07/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		26/09/2016	05/10/2016	No	No