

Brahmi (*Bacopa Monnieri* Linn) in the treatment of dementia

Submission date 04/09/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/09/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/10/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

31/05/2016

Eligibility**Key inclusion criteria**

1. Aged 18 years and over
2. Diagnosis of dementia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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
India
846001

Sponsor information

Organisation
Ambalike Clinic

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ambalike Clinic

Results and Publications

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