

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/09/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/10/2016	<b>Condition category</b> Mental and Behavioural Disorders	<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?

1. Professor Mohan Mishra (scientific)

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2. Dr Ajay Kumar Mishra (public)

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## Contact information

### Type(s)

Scientific

### Contact name

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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

India

846001

**Sponsor information****Organisation**

Ambalike Clinic

**Sponsor details**

Bengali Tol

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Darbhanga

India

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**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?
<a href="#">Basic results</a>		26/09/2016	05/10/2016	No	No