# Dementia - an innovative treatment with Bacopa monnieri Linn

Submission date	Recruitment status	[X] Prospectively registered
17/07/2019	Suspended	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/07/2019	Completed	☐ Results
Last Edited	Condition category	Individual participant data
20/04/2020	Mental and Behavioural Disorders	Record updated in last year

#### Plain English summary of protocol

Background and study aims

Dementia is a major health problem of modern times. Billions of dollars have been poured in its research, but we are no better today than we were years ago. There are various forms of this condition; we have some inkling of their causes but when it comes to treatment we draw a blank. Alzheimer's disease (AD) is the most serious form. Many researchers have hypothesized that if the progression of the milder forms could be slowed down they would not progress to fullfledged AD. But even this assumption may be just wishful thinking. In any case it is not known how to halt this progression, much less to cure it. Classical medicine says that we should first identify the causes and then try to treat it, but this approach may not always work. If a patient presents with high body temperature the physician tries to bring it down even if he is not sure of the cause – a definitive diagnosis can wait. Can we adopt this line of approach in dementias too? Forgetfulness is the cardinal feature of dementia – is it possible to reduce forgetfulness even before diagnosing the root cause? Brahmi is a herb used traditionally in India for a long time as a memory-enhancer, and could be useful in dementia. A pilot study (Brahmi (Bacopa Monnieri Linn) in the treatment of dementia has shown that Brahmi can be very effective in dementia, irrespective of its type or grade (https://www.isrctn.com/ISRCTN18407424). This study is an extension of Phase II of that study.

Who can participate?

Patients aged 18 years and over with dementia

What does the study involve?

Every patient is given an extract of Brahmi (Himalaya) at a dose of 250 mg tablets twice daily orally for three months. Dementia progression is measured before the start of the treatment and again after three months of treatment. After the final evaluation at the end of three months, no further follow-ups are planned.

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 (Bacopa monnieri Linn), but this is very mild.

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

When is the study starting and how long is it expected to run for? May 2019 to December 2022

Who is funding the study? Ambalike Clinic (India)

Who is the main contact?

1. Prof. Mohan Mishra
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2. Dr Ajay Kumar Mishra
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# Contact information

## Type(s)

Scientific

#### Contact name

Prof Mohan Mishra

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#### Type(s)

Public

#### Contact name

Dr Ajay Kumar Mishra

#### Contact details

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

01/2019

# Study information

#### Scientific Title

A Phase II 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 (GDS) and Standardized Mini-Mental State Examination (SMMSE)

#### Acronym

**DITBM** 

#### **Study objectives**

Primary hypothesis:

Brahmi is useful in the treatment of dementia and helps improve Global Deterioration Scale (GDS) score and Standardized Mini-Mental State Examination (SMMSE) 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)

Approved 01/07/2019, Ambalike Clinic Institutional Ethics Committee (Ambalike Clinic, Near Sharma Diagnostics Bengalitola, Laheriasarai, Darbhanga, Bihar, Tel:- +91 (0)9431857477; Email: rashmipriyamishra2009@gmail.com), ref: 01/2019

# 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 will be administered an extract of Brahmi (Himalaya) at a dose of 250 mg tablets twice daily orally for three months. The GDS and SMMSE will be determined before the start of

the treatment and again after three months of treatment. After the final evaluation at the end of three months, no further follow-ups are planned.

#### **Intervention Type**

Drug

#### Phase

Phase II

#### Drug/device/biological/vaccine name(s)

Brahmi (Bacopa monnieri Linn)

#### Primary outcome(s)

Dementia progression measured using the Global Deterioration Scale (GDS) and Standardized Mini-Mental State Examination (SMMSE) at baseline and at the end of 3 months

#### Key secondary outcome(s))

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

#### Completion date

30/12/2022

# 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

01/08/2019

Date of final enrolment 31/07/2022

# Locations

Countries of recruitment India

Study participating centre Ambalike Clinic Bengalitola Near Sharma Diagnostics 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

The datasets will be available at the end of the study from Dr Ajay Kumar Mishra (drakm1969@gmail.com, momishra2006@yhoo.co.in). The data will be anonymised taking care of ethical and legal restrictions. The details, including the types of analyses, will be explained at that time. Written informed consent will be obtained in every case. The researchers hope to keep the data for five years after the end of the study.

# IPD sharing plan summary

Available on request

# **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes