

Dementia - an innovative treatment with *Bacopa monnieri* Linn

Submission date 17/07/2019	Recruitment status Suspended	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/04/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 full-fledged 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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Contact information

Type(s)
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Additional identifiers

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