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Dementia - an innovative treatment with Bacopa monnieri Linn

Submission date
17/07/2019

Recruitment status
Suspended

Registration date
22/07/2019

Overall study status
Completed

Last Edited
20/04/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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2. Dr Ajay Kumar Mishra
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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 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 measure
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

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

Overall study start date
25/05/2019

Completion date
30/12/2022

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
60

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

Sponsor details
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ambalike Clinic

Results and Publications

Publication and dissemination plan
Plan to publish in a high-impact peer-reviewed journal in the year 2024.

Intention to publish date
31/12/2024

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