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Effectiveness of probiotic K10 in managing health outcomes in Parkinson's and Alzheimer's disease

Submission date	Recruitment status	[_] Prospectively registered
19/08/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/08/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/07/2025	Nervous System Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
We developed a clinical trial prior to this one, where we used the probiotic K10 in patients with Alzheimer's disease and obtained excellent results, so we decided to expand the number of patients in a new study, and also include another neurological disease, in this case Parkinson’s disease.

Who can participate?
Adult patients with Parkinson's or Alzheimer's disease.

What does the study involve?
This clinical trial will have 4 arms, being divided into two groups, group 1 with Alzheimer's and group 2 with Parkinson's, one arm of each group will receive probiotic K10 and one arm of each group will receive a controlled placebo.
The main objective of this study is to compare its effect with placebo on cognitive status in individuals with AD and PD, the UPDRS total score in people with early PD and quality of life, and the measurement of caregiver burden in AD and PD. Participants will be randomly assigned to receive a placebo (an inactive substance) and a K10 probiotic (30,000,000 CFU/day). They will be evaluated at baseline, 45 days and 90 days.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Gon1 gestora de projetos (Brazil)

When is the study starting and how long is it expected to run for?
July 2023 to December 2023

Who is funding the study?
1. Micillic Ltd. (Portugal)
2. Gon1 Gestora de Projetos Ltda (Brazil)

Who is the main contact?
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Study website
https://gon1.com.br/DP-DA.html

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
202301

Study information

Scientific Title
Effectiveness of a Probiotic K10 in managing health outcomes in Parkinson’s disease and in early stage (mild cognitive impairment to mild dementia) Alzheimer’s disease

Acronym
K10 PK & AD

Study objectives
Evaluation of the effects of the K10 probiotic mix in patients with degenerative neurological diseases (Parkinson's and Alzheimer's) with a focus on cognitive, motor and psychiatric neurological evaluation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/07/2023, Universidade Vila Velha - ES/UVV (Avenida Comissário José Dantas de Melo, 21, Vila Velha, 29102-920, Brazil; +55 (27) 3421-2063; cep@uvv.br), ref: 6.202.959

Study design
Single-centre double-blind placebo-controlled randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
University/medical school/dental school, Workplace

Study type(s)
Treatment, Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Improvement of symptoms in patients with Parkinson's and Alzheimer's disease

Interventions
In this study, researchers will conduct a randomized, placebo-controlled, phase III trial of a probiotic preparation (Probiotic K10) to evaluate its use as a viable treatment option for neurodegenerative disorders, including Parkinson's disease (PD) and Alzheimer's disease. of Alzheimer (AD). This formulation has been previously demonstrated to improve cognitive function, systemic inflammation, systemic oxidative stress in Alzheimer's patients. The main objective of this study is to compare its effect with placebo on cognitive status in individuals with AD and PD, the UPDRS total score in people with early PD and quality of life, and the measurement of caregiver burden in AD and PD.

Participants will be randomly assigned to receive a placebo (an inactive substance) and a K10 probiotic (30,000,000 CFU/day). They will be evaluated at baseline, 45 days and 90 days. Randomization using an online tool: https://ctrandomization.cancer.gov/tool/

Intervention Type
Supplement

Primary outcome measure
1. Parkinson's group
1.1. Parkinson's Disease rating scale (MDS- UPDRS) at baseline visit, 45 days and 90 days or the time of sufficient disability to require dopaminergic therapy or study closure, whichever occurs first.
1.2. PD quality of life scale (PDQ-39) at baseline visit, 45 days and 90 days or the time of sufficient disability to require dopaminergic therapy or study closure.
1.3. Anxiety levels, mood and caregiver burden in neuropsychiatric evaluation from baseline to T90 or the time of sufficient disability to require dopaminergic therapy or study closure.

2. Alzheimer's group
2.1. Cognitive status measured by brief battery focused on evaluating memory, visuo-spatial skills, constructive skills, language, praxys and attention.
at baseline visit, 45 days and 90 days.
2.2. DA Quality of Life Scale baseline visit, 45 days and 90 days.
2.3. Anxiety levels, mood and caregiver burden in neuropsychiatric evaluation from baseline to T90 or the time of sufficient disability to require dopaminergic therapy or study closure.

Secondary outcome measures
Indirect measurement of emotional stress measured by urinary cortisol dosage at baseline visit, 45 days and 90 days.

Overall study start date
27/07/2023

Completion date
11/12/2023

Eligibility

Key inclusion criteria
Parkinson's arm
1. Presence of all 3 cardinal features of Parkinson's disease (tooth tremor, bradykinesia, and rigidity). Clinical signs must be asymmetrical.
2. Diagnosis of Parkinson's disease within 5 years of the Screening Visit.
3. Age 18 years or older.
4. Women must not be of childbearing potential or must use an approved form of contraception during the trial period.

Alzheimer's arm
1. Men or women between the ages of 60 and 85
2. Diagnosis of probable Alzheimer's disease
3. Portuguese-speaking, English-speaking; Spanish-speaking if the individual site allows
4. Study partner or caregiver to ensure compliance
5. Mini-Mental State Exam score at screening visit greater than 14
6. Stable medical condition for 3 months prior to screening, with no significant abnormal liver, kidney, or blood studies.
7. Able to take oral medications
8. Modified Hachinski Ischemic Index less than or equal to 4
9. CT or MRI from the onset of memory impairment, demonstrating the absence of a clinically significant focal lesion
10. Physically acceptable for this study, as confirmed by medical history, physical examination, neurological examination, and clinical testing

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
104

Total final enrolment
166

Key exclusion criteria
Parkinson's arm:
1. Parkinsonism due to drugs including neuroleptics, alpha-methyldopa, reserpine, metoclopramide, valproic acid.
2. Use of antioxidants (such as selegiline, rasagiline, vitamins E and C), additional supplemental vitamins or minerals, regular use of neuroleptics, chloramphenicol, valproic acid, warfarin.

3. Other parkinsonian disorders.
4. Modified Hoehn and Yahr score of 3 or more on Screening Visit or Baseline Visit.
5. UPDRS tremor score of 3 or greater at Screening Visit or Baseline Visit.
6. History of symptomatic stroke.
7. Sufficient deficiency to require changes in dopaminergic medication treatment during follow-up compared to baseline treatment schedule.
8. Other severe and uncompensated illnesses, including severe psychiatric illnesses.
9. Patients with active cardiovascular, restrictive peripheral vascular, or cerebrovascular disease in the past year.
10. Unstable dose of active CNS therapies.
11. Use of appetite suppressants within 60 days of the Baseline Visit.
12. History of active epilepsy within the past 5 years.
13. Participation in other drug studies or use of other investigational drugs within 30 days prior to the Screening Visit.
14. History of electroconvulsive therapy.
15. History of any brain surgery for Parkinson's disease.
16. History of structural brain disease, such as previous trauma causing damage detected on a CT scan or MRI, hydrocephalus, or previous brain neoplasms.

Alzheimer's arm:
1. Significant neurological disease such as Parkinson's disease, stroke, brain tumor, multiple sclerosis, or seizure disorder
2. Major depression treated in the past 12 months, major mental illness such as schizophrenia, or recent (in past 12 months) alcohol or substance abuse
3. History of invasive cancer within the past two years (excluding non-melanoma skin cancer)
4. Use of any investigational agents within 30 days prior to screening
5. Major surgery within 8 weeks prior to the Baseline Visit
6. Uncontrolled cardiac conditions or severe unstable medical illnesses
7. Antiretroviral therapy for human immunodeficiency virus (HIV)
8. Conditions that will contribute to oxidative stress: current cigarette or cigar smokers (within past month), diabetics on insulin or poorly controlled on oral hypoglycemics
9. Blindness, deafness, language difficulties or any other disability which may prevent the participant from participating or cooperating in the protocol.

Date of first enrolment
28/07/2023

Date of final enrolment
10/08/2023

Locations

Countries of recruitment
Brazil

Study participating centre
Gon1 gestora de projetos
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Micillic Ltd.

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Sponsor type
Other

Website
https://www.micillic.pt

Funder(s)

Funder type
Industry

Funder Name
Micillic Ltd.

Funder Name
Gon1 Gestora de Projetos Ltda

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
20/12/2024

Individual participant data (IPD) sharing plan
The data collected from the volunteers will not be disclosed anonymously in order to preserve the identity and confidentiality defined in the research consent term, the collected data being identified by random numbers and stored on their own servers in an encrypted folder, in case of interest of Access to the data can be requested through the email adm@gon1.com.br or at https://gon1.com.br/ipd and it is mandatory to present a technical justification and complete identification of the requester.

IPD sharing plan summary
Available on request