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Can extended treatment with N-pep-12 improve recovery after acute ischemic stroke?

Submission date 15/04/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/04/2020	**Overall study status** Completed	
Last Edited 19/11/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Cognitive impairment is a common finding in patients with stroke, regardless of severity, with an important impact on the quality of life. Vascular cognitive impairment (VCI) describes a spectrum of cognitive disorders ranging from mild cognitive impairment (MCI) to dementia, with consequences for all cognitive domains and behaviour. This is a study to investigate the effects of N-Pep-12 treatment on the recovery of patients with post-stroke cognitive impairment. N-Pep-12 is a nutritional supplement that has been shown to have neuroprotective and pro-cognitive effects in experimental studies as well as in earlier clinical studies in patients suffering from age-related cognitive deficits.

Who can participate?
Adults aged 18 to 80 with supratentorial ischemic stroke onset 30-120 days before screening

What does the study involve?
Participants are randomly allocated to one of two groups. The first group take N-Pep-12 (90 mg) capsules, once per day, oral, for 360 days, while the second group do not receive any medication. Cognitive function is assessed after 0, 90 and 360 days.

What are the possible benefits and risks of participating?
The potential benefit of N-Pep-12 is improved cognitive function and brain recovery in patients with post-stroke cognitive impairment. The main risk for patients is developing adverse events, which are carefully assessed in order to establish a detailed safety profile of the intervention.

Where is the study run from?
RoNeuro Institute for Neurological Research and Diagnostic (Romania)

When has the study started and how long is it expected to run for?
April 2020 to October 2023

Who is funding the study?
The Society for the Study of Neuroprotection and Neuroplasticity (SSNN) (Romania)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
FSNN20200313

Study information

Scientific Title
Combined neuropsychological, neurophysiological and psychophysiological assessment of the effects of N-Pep-12 on neurorecovery in patients after ischemic stroke - N-Pep-12 Extension

Acronym
N-Pep-12 Extension

Study objectives
The study evaluates the therapeutic effect and the safety of a single daily dose of 90 mg of N-Pep-12 for 360 days in supporting neurorecovery in comparison to a control group of patients after ischemic stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/03/2020, Ethics Committee of the Iuliu Hatieganu University of Medicine and Pharmacy (8 Babeş Street, 400012 Cluj-Napoca, Romania; +40 (0)264 597 256; contact@umfcluj.ro), ref: 115/16.03.2020

Study design
Exploratory prospective randomized open-label controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Supratentorial, radiologically confirmed ischemic stroke with the onset 30-120 days prior to screening

Interventions
Current interventions as of 02/06/2020:
The study is organised into three visits:
Visit 1 – Screening / Baseline - Study Day 0
Visit 2 – Efficacy / Safety - Study Day 90
Visit 3 – Efficacy / Safety - Study Day 360

No follow-up will be performed after the 360-day evaluation.

The study arms will be administered the following treatment courses:
1. Treatment Group: N-Pep-12 (90 mg) capsules 1/ day oral for 360 days
2. Reference Group: will not receive any kind of medication or placebo

Randomisation, Blinding and Unblinding
This is an open-label study. Communication is forbidden between assessments and the person who gives the treatment.
Patients who meet the inclusion and exclusion criteria will be randomly assigned to the treatment group or control group, in a 2:1 ratio.

Previous interventions:
The study is organised into three visits:
Visit 1 – Screening / Baseline - Study Day 0
Visit 2 – Efficacy / Safety - Study Day 90
Visit 3 – Efficacy / Safety - Study Day 360

No follow-up will be performed after the 360-day evaluation.

The study arms will be administered the following treatment courses:
1. Treatment Group: N-Pep-12 (90 mg) capsules 1/ day oral for 360 days
2. Reference Group: will not receive any kind of medication or placebo

Randomisation, Blinding and Unblinding
This is a single-blinded study. Communication is forbidden between assessments and the person who gives the treatment.
Patients meeting the inclusion and exclusion criteria will be randomly assigned to receive active treatment based on the time of their enrollment in the study. Randomisation was performed 2:1 (2 -intervention, 1 -control). The first two patients enrolled will receive active treatment, the third patient will be in the control group. This allocation scheme shall be continued until 90 patients have been enrolled.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
N-Pep-12

Primary outcome measure
1. Cognitive function assessed using Montreal Cognitive Assessment (MoCA) at days 0, 90, 360
2. Emotional status assessed using Hospital Anxiety and Depression Scale at days 0, 90, 360
3. Cognitive function assessed using Digit Span (Wechsler adult intelligence scale – third edition at days 0, 90, 360
4. Cognitive function assessed using Color Trails Test at days 0, 90, 360
5. Cognitive function assessed using PSI (Processing Speed Index, Wechsler adult intelligence scale – third edition) at days 0, 90, 360

Secondary outcome measures
1. Safety variables:
1.1. Adverse events/serious adverse events measured using a questionnaire at 90 and 360 days
1.2. Mortality reported at any time during the study
2. Subgroup analysis:
2.1. Eye movements assessed using a Tobii Pro TX300 eye tracking device and analyzed using Tobii Studio software at days 0, 90, 360
2.2. Brain electrical activity assessed using electroencephalography (EEG) and analyzed quantitatively using BrainAnalyzer software at days 0, 90, 360

Overall study start date
13/03/2020

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Stroke onset 30-120 days prior to screening
2. Stroke is ischemic in origin, supratentorial, and radiologically confirmed (CT or MRI)
3. No significant pre-stroke disability (pre-stroke Modified Rankin Score of 0 or 1)
4. Goodglass and Kaplan Communication Scale Score of > 2 at screening
5. No other radiologically confirmed stroke in the 3 months preceding index stroke
6. Age between 18 and 80 years, inclusive
7. Signed informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
90

Total final enrolment
107

Key exclusion criteria

1. Pre-existing and active major neurological disease
2. Pre-existing and active (e.g., on chronic medication) major psychiatric disease, such as major depression, schizophrenia, bipolar disease, or dementia (the short Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) score >3)
3. Advanced liver, kidney, cardiac, or pulmonary disease
4. A terminal medical diagnosis consistent with survival < 1 year
5. Major drug dependency, including alcohol (in the investigator's judgment)
6. Injury of writing hand influencing cognitive or other outcome measures, in the investigator's judgment
7. Females who are pregnant or lactating

Date of first enrolment
30/04/2020

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
Romania

Study participating centre
RoNeuro Institute for Neurological Research and Diagnostic
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Sponsor information

Organisation
The Foundation for the Study of Neuroscience and Neuroregeneration (Fundatia pentru Studiul Nanoneurostiintelor si Neuroregenerarii)

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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
The Foundation for the Study of Neuroscience and Neuroregeneration (Fundatia pentru Studiul Nanoneurostiintelor si Neuroregenerarii)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Additional documents will be made available at a later date.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	13/03/2020	20/10/2023	No	No
Results article		28/09/2024	19/11/2024	Yes	No