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Effects of N-Pep-12 on neurorecovery in patients after traumatic brain injury

Submission date
16/03/2026

Recruitment status
Recruiting

Registration date
30/03/2026

Overall study status
Ongoing

Last Edited
24/08/2026

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Previous research has found that the peptides in N-PEP-12 exhibit qualities similar to those seen in naturally occurring peptide growth factors, such as increasing neurite outgrowth, improving neuronal survival, and protecting against metabolic stress. This study's rationale is based on these previously documented properties that have the potential to impact the attentional performance, cognition, and mental well-being of patients after traumatic brain injury (TBI).

Who can participate?
Patients aged between 18 and 80 years with mild, moderate, or severe TBI confirmed following a neurological/neurosurgical medical consultation.

What does the study involve?
Three visits for clinical evaluation, over a period of 180 days. The subjects will be part of two groups (N-PEP-12 and no medication).

What are the possible benefits and risks of participating?
Potential benefits include the possibility of receiving treatment with Cebrium, which will be administered with a 50% probability and may contribute to improvements in cognitive function. However, individual participants may not directly benefit from participation. The study may contribute to the development of improved therapeutic strategies for patients with TBI.

Participation in this study involves minimal risk. Neurophysiological assessments, including eye-tracking and quantitative EEG, as well as neuropsychological testing, are non-invasive and are not expected to pose significant risk or discomfort.

Where is the study run from?
Foundation of the Society for the Study of Neuroprotection and Neuroplasticity (SSNN) (Fundatia pentru Studiul Nanoneurostiintelor si Neuroregenerarii), Romania.

When is the study starting and how long is it expected to run for?
April 2026 to October 2028.

Who is funding the study?
Foundation of the Society for the Study of Neuroprotection and Neuroplasticity (SSNN) (Fundatia pentru Studiul Nanoneurostiintelor si Neuroregenerarii), Romania.

Who is the main contact?
Prof Fior-Dafin Muresanu, dafinm@ssnn.ro

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Additional identifiers

Study information

Scientific Title
Combined neuropsychological, neurophysiological and psychophysiological assessment of the effects of N-Pep-12 on neurorecovery in patients after traumatic brain injury

Acronym
NPEP-TBI

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/03/2026, Ethics Committee UMF ''Iuliu Hatieganu'' Cluj Napoca (8 Victor Babes Street, Cluj Napoca, 400354, Romania; +40 0264-597256; etica.cercetare@umfcluj.ro), ref: DEP10 /19.01.2026

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment

Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Neurorecovery in patients after traumatic brain injury

Interventions
This study is a prospective, randomized, controlled, single-blind clinical study designed to evaluate the effects of N-Pep-12 dietary supplementation (MemoProve/Cebrium) on neurocognitive recovery in patients with traumatic brain injury (TBI).

A total of 200 participants will be enrolled and randomly assigned in a 1:1 allocation ratio to one of two study arms using block randomization (4 blocks) according to ICH E9 principles.

Participants in the intervention group (n = 100) will receive N-Pep-12 at a dose of 90 mg once daily, administered orally as a dietary supplement for 180 days.

Participants in the control group (n = 100) will receive no dietary supplementation and will continue with standard clinical care only.

Intervention Type
Supplement

Primary outcome(s)
1. Global cognitive function measured using Montreal Cognitive Assessment (MoCA) at days 0, 90 and 180

2. Symptoms of anxiety and depression measured using Hospital Anxiety and Depression Scale (HADS) at days 0, 90 and 180

3. Working memory and attention measured using Digit Span (DS) at days 0, 90 and 180

4. Executive function and attention measured using Color Trial Test (CTT) at days 0, 90 and 180

5. Processing speed measured using Processing Speed Index (PSI) at days 0, 90 and 180

6. Verbal learning and memory measured using Rey Auditory Verbal Learning Test (RAVLT) at days 0, 90 and 180

Key secondary outcome(s)

Completion date
01/10/2028

Eligibility

Key inclusion criteria

1. Patients with mild, moderate, or severe traumatic brain injury (TBI) confirmed following a neurological/neurosurgical medical consultation.
2. Patients in the post-acute stage of TBI, at least 30 days after the traumatic brain injury, with a stable clinical status.
3. Presence of residual cognitive and/or affective dysfunction, documented through neuropsychological evaluation
(e.g., MoCA and/or HADS) and/or persistent subjective neurocognitive complaints.
4. Isolated traumatic brain injury (AIS score ≤ 2 in other body regions).
5. Pre-injury Karnofsky Performance Status = 100.
6. Age between 18 and 80 years.
7. Patient able to provide written informed consent for participation in the study.
8. Patient willing and able to comply with the protocol requirements throughout the study duration.
9. Women of childbearing potential must have a negative urine pregnancy test and agree to use adequate contraception.
10. The patient must have been able to speak, read, and write prior to the accident.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Polytrauma patients (AIS score > 2 in other body regions).
2. Patients with spinal cord injuries.
3. Major active psychiatric disorders (e.g., major depression, schizophrenia, bipolar disorder, including patients receiving chronic treatment for these conditions).
4. Advanced hepatic, renal, or pulmonary disease.
5. Terminal medical diagnoses compatible with a life expectancy < 1 year.
6. Major substance dependence, including alcohol (according to the investigator’s opinion).
7. Injury to the dominant writing hand, which could influence cognitive measurements or test results (according to the investigator’s opinion).

Date of first enrolment
01/04/2026

Date of final enrolment
01/04/2028

Locations

Countries of recruitment
Romania

Sponsor information

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

Funder(s)

Funder type

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			24/08/2026	No	No