ISRCTN11086312 https://doi.org/10.1186/ISRCTN11086312

Effect of vitamin D supplementation on the functional efficiency of patients after stroke

Submission date	**Recruitment status**	[_] Prospectively registered
16/02/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/03/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2025	Circulatory System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Stroke is the third leading cause of death in the adult population after heart disease and cancer. Post-stroke death rates in Poland are higher than in other European countries and the USA. Long-term disability is a serious problem among survivors. Studies have shown that almost 15-30% of people after a stroke are permanently disabled, and more than 20% of people require institutional help 3 months after the stroke. Vitamin D deficiency is now a widely recognized public health problem, affecting almost every second person worldwide. Recent evidence from multiple population studies indicates that vitamin D deficiency is a predictor of future strokes. The aim of this study is to find out whether vitamin D supplementation has an impact on patients undergoing neurological rehabilitation over 6 weeks.

Who can participate?
Patients aged 45-65 years who have had their first ischemic stroke and have been admitted to the ward for early post-stroke rehabilitation

What does the study involve?
Participants will undergo examinations including medical history, history and physical examination, and basic laboratory tests. They will be randomly allocated to one of two groups to take vitamin D supplements every morning (at 7.30 a.m.) for 6 weeks or to not take vitamin D supplements. Participants are assessed at the beginning of hospitalization and after 42 days.

What are the possible benefits and risks of participating?
For the safety of patients, blood pressure and heart rate will be measured before each unit of rehabilitation. Improvement training will always be selected individually for each patient to their current capabilities and needs, taking into account the patient's capabilities. Each of the patients qualified for rehabilitation in the Local Department of Neurological Rehabilitation may withdraw from participation in rehabilitation.
The results of the study will be used to participate in the discussion on modern forms of therapy used in patients after a stroke, their effectiveness, and the possibility of practical use on a wider scale.

Where is the study run from?
Regional Specialist Hospital in Wrocław, Local Department of Neurological Rehabilitation (Poland)

When is the study starting and how long is it expected to run for?
December 2022 to December 2023

Who is funding the study?
Wroclaw Medical University (Poland) - SUBZ.E060.23.037

Who is the main contact?
Prof. Małgorzata Paprocka-Borowicz, malgorzata.paprocka-borowicz@umw.edu.pl

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

The effect of vitamin D Supplementation on the fUnctional efficiency of Patients after ischemic strOke undergoing neurological Rehabilitation - a prospective, randomized Trial with a control group (D-SUPORT)

Acronym
D-SUPORT

Study objectives
Vitamin D (25[OH]D) supplementation improves the functional efficiency of patients undergoing 6-week neurological rehabilitation better than no supplementation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/02/2023, Institutional Review Board at Wroclaw Medical University (ul. Pasteura 1, 50-367 Wrocław, Poland; +48 (0)71 784 17 10; bioetyka@umed.wroc.pl), ref: KB – 813/2022

Study design
Single-center non-placebo-controlled prospective randomized study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Patients who had their first ischemic stroke were admitted to the ward for early post-stroke rehabilitation

Interventions
Participants in the study will be randomized (using the randomization program from the website random.org) and assigned to one of two comparison groups: group A - a group in which vitamin D supplementation at a dose of 2000 IU every morning (at 7.30 a.m.) for 6 weeks and group B (control) - group without vitamin D supplementation.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
25-hydroxyvitamin D (25[OH]D)

Primary outcome measure
1. Clinical symptoms in the course of stroke were assessed using the National Institute of Health Stroke Scale (NIHSS) at baseline and after the intervention and 1 and 3 months after the intervention
2. Everyday activity assessed using the Barthel Scale at baseline and after the intervention and 1 and 3 months after the intervention
3. Degree of disability assessed using the Modified Rankin Scale at baseline and after the intervention and 1 and 3 months after the intervention

Secondary outcome measures
Complete blood count, urine analysis, and concentration of 25(OH)D and IGF-1 measured using basic laboratory tests before and after the intervention at baseline and after the intervention and 1 and 3 months after the intervention

Overall study start date
01/12/2022

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. First ischemic stroke (time of occurrence 2 weeks before admission to the Department of Neurological Rehabilitation)
2. Stroke confirmed by MR or CT scan
3. Age >18 years old
4. No contraindications to participate in the experiment (consent of the attending physician)
5. No concomitant neurological diseases
6. Written informed consent of the patient to participate in the research

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

120

Total final enrolment
160

Key exclusion criteria
1. Patients with infection in the last 2 weeks
2. Patients who have taken vitamin D and its derivatives or calcium in the last 3 months
3. Patients with liver and kidney disorders
4. Patients with thyroid dysfunction
5. Patients with aphasia
6. Patients who do not consent to the research

Date of first enrolment
01/03/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
Poland

Study participating centre
Regional Specialist Hospital in Wrocław Local Department of Neurological Rehabilitation
Poświecka 8 Street
Wrocław
Poland
51-128

Sponsor information

Organisation
Wroclaw Medical University

Sponsor details
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Sponsor type

University/education

Website
https://www.umw.edu.pl/pl/jednostki/katedra-fizjoterapii

Funder(s)

Funder type
University/education

Funder Name
Uniwersytet Medyczny im. Piastów Slaskich we Wroclawiu

Alternative Name(s)
Wroclaw Medical University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

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

Intention to publish date
31/01/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are available from Prof. Małgorzata Paprocka-Borowicz (malgorzata.paprocka-borowicz@umw.edu.pl) upon reasonable request. Raw data (taking into account the anonymity of patients) will become available from the end of the study for 5 years. The research results will be passed on to other researchers in order to compare these results with the results of their own research.

IPD sharing plan summary
Available on request