Longitudinal observational study to assess the nutritional status of patients with an acute ischemic stroke

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49561

Source
ToetsingOnline

Brief title
SNIT

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
ischemic stroke

Health condition

ischemische beroerte

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Nutricia Research BV

Intervention

Keyword: Nutritional status, Observational, Stroke

Outcome measures

Primary outcome

Main study parameters/outcome of the study:

- Nutrient and fluid intake over time

- Biomarkers of vitamin and mineral status over time

Secondary outcome

Other study parameters/outcome of the study (if applicable):

- Questionaires and biomarkers of malnutrition over time

Study description

Background summary

Stroke is described by a poor blood flow to the brain resulting in cell death and as such stroke is a leading cause of mortality. Across European countries incidence rates vary between 100-700 per 100,000 inhabitants. There are two main types of stroke: an ischemic stroke causing a poor blood flow due to a lack of blood flow with an incidence rate between 65-85% and hemorrhagic stroke causing a poor blood flow due to bleeding. Stroke patients suffer from multiple factors that may influence dietary intake. Hence, stroke is an important contributor for the development or deterioration of malnutrition in the patient. The incidence of malnutrition after stroke has been shown to range from 6-62% depending on the population that has been studied. However, data on nutritional status and specific deficiencies are limited in this patient group. The goal of this study is to learn more about the nutritional status of patients with an ischemic stroke, both with and without dysphagia, during hospitalization immediately after stroke incidence and during rehabilitation in

the first months after hospital discharge.

Study objective

The main objective of this study is to obtain insight in the nutrient and fluid intake and nutrient and biomarker concentrations in the blood of patients after an acute ischemic stroke during initial hospital care until 13 weeks after hospital admission

Study design

This is an observational, multi-centre, longitudinal study in 50 subjects with an acute ischemic stroke.

Study burden and risks

For patients questionnaires will be administered and at home they have to complete a 3-day dietary intake diary twice. In addition blood will be collected 4 times.
Subjects should comply with the instructions not to donate blood during study participation and to be fasted at the time of blood withdrawal (which means not to eat and drink at least 7 hours before; drinking of water is allowed up to 1 hour before sampling).
Results of the study will provide insight in the nutritional status of the subjects. This information will be very useful for future monitoring of stroke patients and the possibility to provide additional nutritional advice or supplements to prevent deficiencies.
The burden is considered minimal and in our opinion, the benefits of a potential better nutritional status for future patients outweigh the burden of this study.
In addition, blood parameters will be analysed after the end of the study. Results will be shared with the study team in the hospital and reviewed by a physician on clinical relevance. In case of clinically relevant deviations the subject and his/her General Practitioner will be informed of this.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subjects with an acute ischemic stroke (with and without dysphagia):
- Age * 50
- Diagnosis of ischemic stroke
- Included for participation in the study within 24h after admission.

Exclusion criteria

Subjects with an acute ischemic stroke (with and without dysphagia):
- History of progressive neurological disorders (e.g. Parkinson*s disease, dementia, multiple sclerosis).
- Receiving any cancer treatment within 1 year before entry into the study (signing of informed consent).
- Blood donation or receiving blood transfusion within 4 weeks before entry into the study (informed consent) and/or planned blood donation during the study
- Traumatic brain injury
- Diagnosis of haemorrhagic stroke (subarachnoid or intracerebral) or transient ischemic attack at hospital admission
- Any medical condition that significantly interferes with digestion and/or gastrointestinal (GI) function except for dysphagia (e.g. short bowel syndrome, inflammatory bowel disease, gastric ulcer, gastritis (gastro)enteritis, GI

cancer) as judged by the investigator.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	18-10-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-05-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-10-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	20-08-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL59614.068.17