Nutritional status in stroke patients

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25690

Source
NTR

Brief title
NUST

Health condition

Nutritional status after an ischemic stroke in patients in a rehabilitation centre.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Nutritional status

Secondary outcome

Demographics, Quality of life, Activities daily living score, level of malnutrition and stroke characteristics (in patient group).

Study description

Background summary

The NUST study is an observational study in which the nutritional status of ischemic stroke patients with and without dysphagia in the rehabilitation phase will be compared to healthy reference subjects.

The primary outcome parameter will be the nutritional status. The secondary outcome parameters will be demographics, subject characteristics and stroke characteristics.

The study is a multi-centre study and will be performed in Germany.

Study objective

The nutritional status in the stroke rehabilitation group is unequal to nutritional status in age- and sex-matched healthy reference group.

Study design

Time points of the outcome; Visit 0 (screening) Visit 1 (Day 7).

Intervention

Not applicable, this is an observational study

Contacts

Public
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Scientific
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Eligibility criteria

Inclusion criteria

Inclusion criteria patients:

1. Diagnosis of ischaemic stroke

2. Time after stroke: ¡Ý 2 and ¡Ü 12 weeks

3. Inpatient in a stroke rehabilitation centre

4. Age ¡Ý 50 and ¡Ü 75 years

5. Written informed consent

Inclusion criteria healthy subjects:

1. Body Mass Index (BMI): ¡Ý 20 and < 30 kg/m2

2. Written informed consent

Exclusion criteria

Exclusion criteria patients:

1. Diagnosis of haemorrhagic stroke

2. Known history of progressive neurological disorders (e.g. Parkinson¡¯s disease, MS)

3. Dysphagia not related to stroke

4. Receiving chemo- or radiotherapy within 1 year prior to entry into the study

5. Receiving tube feeding or has been receiving tube feeding within 2 weeks prior to entry into the study

6. Current prescription of vitamin injection

7. Investigator¡¯s uncertainty about the ability to adhere to the protocol requirements because of the condition of the patient

8. Participation in any other study involving investigational or marketed products within 6 weeks prior to entry into the study

Exclusion criteria healthy subjects:

1. Having a special diet, e.g. receiving oral nutritional support or tube feed, or having a dysphagia-adapted diet, vegan diet or ketogenic diet

2. Known diabetes mellitus type 2

3. Known disorders of the GI tract, including coeliac disease

4. Known history of cardiovascular or cerebrovascular disease, e.g. myocard infarct, stroke or transient ischaemic attack

5. Use of anti-hypertensive or cholesterol- or triglyceride-lowering drugs

6. Hospital admittance (with overnight stay) within 6 months prior to entry into the study

7. Receiving chemo- or radiotherapy within 1 year prior to entry into the study

8. Decrease in appetite and/or food intake within 4 weeks prior to entry into the study

9. Known weight loss of >3 kg in the last 3 months

10. Participation in weight loss diet within 3 months prior to entry into the study

11. Current moderate or heavy alcohol use (>14 consumptions per week for females or >21 consumptions per week for males), moderate or heavy smoking (¡Ý10 cigarettes or ¡Ý5 cigars/pipes per day) or drug abuse to the opinion of the investigator

12. Blood donation within 4 weeks prior to entry into the study

13. Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements

14. Participation in any other clinical study involving investigational or marketed products within 6 weeks prior to entry into the study

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-12-2017
Enrollment:	0
Type:	Unknown

Ethics review

Positive opinion

Date:	06-11-2017
Application type:	First submission

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
NTR-new	NL6625
NTR-old	NTR6802
Other	Nutricia Research : MPR16TA07987

Study results