Nutritional status in stroke patients

Gepubliceerd: 06-11-2017 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25690

Bron
NTR

Verkorte titel
NUST

Aandoening

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

Ondersteuning

Primaire sponsor: Danone Nutricia Research
Overige ondersteuning: Danone Nutricia Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Nutritional status

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Not applicable, this is an observational study

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-12-2017
Aantal proefpersonen:	0
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	06-11-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6625

Register	ID
NTR-old	NTR6802
Ander register	Nutricia Research : MPR16TA07987

Resultaten