Structured modified Rankin Scale study

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

Samenvatting

ID

NL-OMON26434

Bron
Nationaal Trial Register

Verkorte titel
mRS study

Aandoening

Subarachnoid hemorrhage

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1) the inter-rater variability in outcome assessment using the mRS with different assessment methods (assessment by physician, assessment by a structured interview or self-assessment) for adult patients with an aSAH

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The modified Rankin Scale (mRS) is a scale measuring disability and is validated for use in patients with stroke. Measurement properties of the mRS are not known for patients with aneurysmal subarachnoid hemorrhage, despite its extensive use in trials and in the national quality registry.
Objective: To investigate the inter-rater variability in outcome assessment using the mRS with different assessment methods for adults with an aneurysmal subarachnoid hemorrhage (aSAH). Furthermore we aim to explore what causes possible differences in outcome scores and whether the mRS can be substituted by a self-assessed mRS. Additionally, we explore the responsiveness of the mRS between six weeks and six months using the SS-QoL as an anchor. Finally, we explore the correlation between the mRS and three PROMs to study the convergent validity of the mRS in patients with aneurysmal subarachnoid hemorrhage.
Study design: This is a prospective, multicenter study, in which patients admitted with a subarachnoid hemorrhage caused by a ruptured aneurysm will be included. During the regular follow-up visits on six weeks and six months the mRS will be assessed by their treating physician and either by a structured interview or by a self-assessment and compared with online completed PROMs.
Study population: Patients admitted with an aneurysmal subarachnoid hemorrhage and age ≥ 18 years will be screened for eligibility. Exclusion criteria are patients who passed away, an unclear diagnosis, patients not able to visit the outpatient clinic or patients who do not speak the Dutch language.
Intervention: Subjects will be treated according to local standards of care. During their outpatient visits their treating physician will score the mRS during the patient visit, scoring by a nurse/student through a structured face-to-face interview or a self-assessment of the mRS is applied. The patients will also be invited for completion of the EQ-5D-5L, SS-Qol and RAND-36. Physicians and nurses/students will be blinded for the record obtained by the other assessment.
Main study parameters / endpoints: Demographic data will be retrospectively collected including age, gender, World Federation of Neurosurgical Societies grading system (WFNS) at admission, the modified Fisher score and location of the aneurysm. The modified Rankin Scale is a global disability scale which has an ordinal 7-point scale ranging from 0 to 6.(1) The modified Rankin Scale can be assessed by a structured interview, which has been translated to Dutch by Janssen et al with the standard procedure for forward-backward translation.(2) Self assessment will take place during the outpatient visit by an online form which is based on the structured interview before mentioned. At the same visit patients complete the online EQ-5D-5L, SS-QoL and RAND-36 questionnaire.

Doel van het onderzoek

We hypothesize that the interrater reliability is moderate (κ = 0.4 – 0.6) between the assessment of the physician and the structured interview and that the interrater reliability is moderate (κ = 0.4 – 0.6) between the assessment of the physician and the self-assessment.

We hypothesize that the structured interview and self-assessment are equivalent.

We expect a moderate correlation (Spearman rank 0.4-0.6) between mRS and SS-QoL.
Our hypothesis is that the correlation between assessment with structured interview or self-assessment of the mRS compared with the SS-QoL is higher than the correlation between the physicians' assessment and the SS-QoL. Furthermore we expect the score on the EQ-5D-5L to correlate higher with the physicians' assessment of mRS than with the structured or self-assessment of the mRS due to less details concerning cognition, concentration and fatigue incorporated in the EQ-5D-5L than in the SS-QoL. We expect the mRS to correlate higher with the Physical Component Score of the RAND-36 than with the Mental Component Score of the RAND-36.
We expect to find a ceiling effect of the mRS compaired to all three PROMs, however we expect this to be the most apparent on the SS-Qol, since it is developed to capture stroke specific symptoms.

We hypothesize that the responsiveness of the mRS shows a moderate correlation (0.4 – 0.6) with the SS-QoL, the RAND-36 and the EQ-5D-5L. We expect a higher correlation between the SS-QoL, RAND-36 and EQ-5D-5L and the GPE than between the mRS and the GPE.

Onderzoeksopzet

- approximately six to eight weeks after hospital discharge after the subarachnoid hemorrhage
- approximately six months after hospital discharge

Onderzoeksproduct en/of interventie

During the regular outpatient follow-up visit, approximately six to eight weeks after their discharge and approximately six months after discharge, the mRS will be assessed by:
- their treating physician for all included patients.
- 50 percent of patients go through a structured interview by an independent nurse/student and 50 percent of patients will complete self-assessment of the mRS using an online form during the visit or at home. At the end of the self-assessment the patients will answer questions about the feasibility of the self-assessment.
- at six months the Global Perceived Effect is added to the abovementioned questionnaires.
Comparison will be made by a completed EQ-5D-5L, RAND-36 and short version of the Stroke Specific Quality of Life Scale (SS-QoL). Completion of these questionnaires can be done on paper or digital during the outpatient visit or at home, depending on the choice of the treating center.
Patient will be randomized for study arm. Physicians and nurses/students will be blinded for the record obtained by the other assessor.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Diagnosis of an aneurysmal subarachnoid hemorrhage according to treating neurologist or neurosurgeon.
- Age ≥ 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Subjects that died during hospital admission or before the first follow-up measure.
- Unclear diagnosis.
- Patients who are not able to visit the outpatient clinic for their regular follow-up visit.
- Patients who do not speak the Dutch language.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-07-2019
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	NL7859
Ander register	METC Radboudumc : 2018-4184

Resultaten