Prognosis and quality of life in patients with aphasia: a prospective follow-up study.

Published: 07-11-2006
Last updated: 14-05-2024

A. PrognosisThe first aim of this study is to gain insight in the recovery pattern of the linguistic levels (i.e. semantics, phonology and syntax) in aphasia due to stroke. Information on the frequency of the occurrence of linguistic deficits in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30397

Source
ToetsingOnline

Brief title
Sequential Prognostic Evaluation of Aphasia after stroKe (SPEAK).

Condition

- Central nervous system vascular disorders

Synonym
Aphasia, language disorder

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NWO;Mozaiek

Intervention

Keyword: aphasia, prognosis, recovery, stroke

Outcome measures

Primary outcome

A. Prognosis

The primary outcome measure is the severity of the linguistic deficits at several time points in the first year post-stroke, measured with the ScreeLing, a test that measures functioning on three linguistic levels: semantics, phonology and syntax.

B. Quality of Life

The primary outcome measure concern the quality of life as measured with the Health Utilities Index at several time points in the first year post-stroke.

Secondary outcome

A. Prognosis

The secondary outcome measures are the severity of aphasia measured with the Token Test and the verbal communication measured with the Aphasia Severity Rating Scale, at several time points in the first year post-stroke. In addition, the extent of the recovery of aphasia and the performance in the non-linguistic cognitive domains at 3 months and at one year post onset.

B. Quality of life

The secondary outcome measures are the EuroQol, the modified Rankin Scale and

the Barthel Index, which are respectively related to the quality of life and

daily life functioning, measured at several time points in the first year

post-stroke.

Study description

Background summary

The prevalence of aphasia is approximately 20-25% among all stroke patients. Information on the rate and degree of the recovery of aphasia is very important. Patients and family want to have insight in the disorder, prognosis and therapeutic possibilities as soon as possible. Prognostic information is of clinical importance too, because it may affect our choices concerning rehabilitation facilities. There are indications that the initial severity of the language disorder during the first week post onset predicts the outcome of aphasia at one year after stroke. However, a detailed study of the recovery pattern of the various linguistic levels is not available. Lesion size and lesion location are also thought to be important factors in aphasia recovery just as the initial stroke severity. Many studies agree that quality of life is negatively affected by aphasia. However, there are no specific data on the exact relationship between aphasia and quality of life.

Study objective

A. Prognosis
The first aim of this study is to gain insight in the recovery pattern of the linguistic levels (i.e. semantics, phonology and syntax) in aphasia due to stroke. Information on the frequency of the occurrence of linguistic deficits in patients with aphasia and the course during recovery is lacking. The recovery pattern of the linguistic levels has to be analyzed against the background of co-existing cognitive disorders. The presence of cognitive disorders is reported to interfere with functional outcome. The research questions are:

1. What is the recovery pattern of the linguistic disorders (i.e. semantics, phonology and syntax) in patients with aphasia due to stroke and what is the final outcome?
2. What is the influence of the initial specific linguistic disorders on the prognosis?
3 a. Does the rate of recovery on one or more linguistic levels predict the outcome of linguistic functioning at one year? b. If so, which period is crucial in predicting the outcome at one year?

4. Which factors including non-linguistic cognitive deficits, stroke severity, lesion size and location, influence the recovery of the linguistic disorders?

B. Quality of Life
The second aim of this study is to investigate the influence of linguistic deficits on the quality of life. The research questions are:

1. Does the quality of life evolve over time?
2. Is there an association between the recovery pattern on (one of) the linguistic levels and the quality of life?
3. In which period during recovery, and with which linguistic levels is this association the strongest?
4. Which factors such as linguistic and non-linguistic cognitive deficits are associated with quality of life?

Study design

This study is an observational prospective follow-up study. Patients with aphasia due to stroke (n=200) will be assessed from two days until one-year post onset.

Study burden and risks

Participants will receive an evaluative assessment six times during a one-year follow-up including language, daily life functioning and quality of life tests. Participants will be tested at 2-6 days post-onset, at 7-14 days, at 6 weeks, at 3 months, at 6 months and finally at one year post-onset. At 3 months and at one-year post onset participants will also be assessed with a neuropsychological examination. All assessments will be held on the same day as the regular visits to the speech therapist as much as possible so that participants don*t have to come on an extra visit. If necessary, patients will be visited at home. Each assessment takes about one hour to complete, so the total extra time for each participant during the one-year follow-up is about 6 hours. The assessments are not associated with any risk. All included tests are widely used in daily practice and also in follow-up studies. The difference is that in our study participants will be assessed at specific moments starting from the acute phase.
Participants benefit a lot from this study, since they will gain insight in their recovery pattern during the first year post-stroke. Cognitive disorders that are detected will be described to the speech therapist, since they can effect the treatment of the language disorder. As a result the speech therapy can be adjusted so that the participant will receive the most optimal treatment. Thus, participants are ensured of a good follow-up inspection and also a good guidance of the patient, family and speech therapist.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 1738
3000 DR Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 1738
3000 DR Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Stroke patients with aphasia < six days post onset; Age 18 years or more; Language near native; Testable with the ScreeLing within six days post onset.

Exclusion criteria

Prior stroke and/or aphasia; (suspected) Dementia; Severe dysartria and/ or verbal apraxia; Developmental dyslexia; Severe perceptual, visual and/or hearing deficit; Stroke due to a subarachnoidal hemorrhage; Illiteracy; Recurrent stroke; Recent psychiatric history.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2007
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	07-11-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL11047.078.06