PRACTISE: Promoting acute thrombolysis for ischemic stroke.

Gepubliceerd: 22-09-2005 Laatst bijgewerkt: 18-08-2022

The purpose of this study is: 1. To evaluate the effect of a high intensity implementation strategy compared to a regular intensity strategy; 2. Identify success factors and obstacles for mplementation of thrombolysis; and 3) to assess the cost-...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28863

Bron
Nationaal Trial Register

Verkorte titel
PRACTISE

Aandoening

Stroke

Ondersteuning

Primaire sponsor: Erasmus MC Rotterdam
Overige ondersteuning: ZON MW
Postbus 93245
2509 AE Den Haag

Website: www.zonmw.nl

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Treatment with thrombolysis or not in all registered patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Thrombolysis with rt-PA is an effective treatment for patients with ischemic stroke within 3 hours from onset. More than 25% of stroke patients arrive in time to be treated with thrombolysis. Nevertheless, in most hospitals, only 1 to 8% of all stroke patients are treated. Professional, organizational and contextual barriers are hampering broad implementation. The purpose of this study is:

1. to evaluate the effect of a high intensity implementation strategy compared to a regular intensity strategy;

2. identify success factors and obstacles for implementation of thrombolysis; and

3. to assess the cost-effectiveness of thrombolysis in routine daily Dutch neurological care settings, taking into account the costs of implementation.

Methods:

The effect of the implementation will be evaluated in a cluster randomized, controlled design. Randomization will be done on the hospital level, with pairwise stratification for thrombolysis rate, size and type of hospital (academic or non-academic, and regional versus urban).

Primary outcome:

the number of thrombolyses in the high intensity versus the regular intensity group.

Secondary outcomes:

the rate of symptomatic intracebral hemorrhages among thrombolysed patients, the

proportion of patients admitted within 3 hours from onset of symptoms, and health status at 3
months. Twelve centers will participate, yielding a two-armed trial of 3500 stroke
patients per arm. This is sufficient to a detect a 50% increase in thrombolysis rate in centers with the high intensity intervention compared to regular intensity intervention, and a twofold increase in the rate of symptomatic intracerebral hemorrhage in thrombolysed patients, with adjustment for intracluster correlation.
The implementation strategy is based on the Breakthrough methodology, preceded by an in-depth analysis of obstacles from a regional and national point of view. A tool kit with improvement actions to be used by the vascular neurologist, the change agent,
will be developed and introduced. The improvement actions will include the FAST
test for GP's and ambulance personnel, a less strict set of contra-indications derived
from a Delphi panel of international experts,1 tools to improve the "door to needle time", and tools for dealing with issues of decision making under conditions of uncertainty.

The implementation process will be monitored by means of the Assertive Community Treatment approach, according to prespecified criteria, in order to identify obstacles and success factors for implementation of thrombolysis.

The results will be analyzed with a logistic regression model with a random parameter for center effect.

Doel van het onderzoek

The purpose of this study is:

1. To evaluate the effect of a high intensity implementation strategy compared to a regular intensity strategy;

2. Identify success factors and obstacles for mplementation of thrombolysis; and 3) to assess the cost-effectiveness of thrombolysis in routine daily Dutch neurological care settings, taking into account the costs of implementation.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

The high intensity intervention consists of the introductionof a set of implementation tools, directed at the four levels where barriers against trombolysis are expected. This toolkit will be explained in a training sessions to the vascular neurologist and coordinating nurse in each

center, who also act as the local agents of change. Training session takes place after 6 months and 1 year.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients who are admitted with acute stroke, i.e. patients with an acute focal neurological deficit, which cannot be explained by a condition other than stroke, andonset of symptoms not longer than 24 hours ago, will be included in the trial. Thesepatients will be registered, and a minimal set of baseline data will be recorded. Patients with acute stroke, who are admitted within 4 hours from onset of symptoms will be registered and followed up after three months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Age under 18.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2005
Aantal proefpersonen:	7000
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	22-09-2005
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	NL273
NTR-old	NTR311
Ander register	: 945-14-217
ISRCTN	ISRCTN20405426

Resultaten

Samenvatting resultaten
Trial protocol on trial website.