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Promoting acute thrombolysis for ischemic stroke

Submission date	Recruitment status	[_] Prospectively registered
24/06/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/11/2013	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.practise-trial.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
945-14-217

Study information

Scientific Title

Acronym
PRACTISE

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
The high intensity intervention consists of the introduction of a set of implementation tools, directed at the four levels where barriers are expected. This toolkit will be explained in a training session 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.

Control: regular intensity strategy

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Treatment with thrombolysis or not in all registered patients

Secondary outcome measures
Admission within 3 hours after onset of symptoms, death or disability at three months (in the subgroup of patients with ischemic stroke who were admitted within 3 hours).

Overall study start date
01/08/2005

Completion date
01/08/2007

Eligibility

Key inclusion criteria
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, and onset of symptoms not longer than 24 hours ago

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
7,000

Key exclusion criteria
Age under 18

Date of first enrolment
01/08/2005

Date of final enrolment
01/08/2007

Locations

Countries of recruitment

Netherlands

Study participating centre
PO Box 1738
Rotterdam
Netherlands
3000 DR

Sponsor information

Organisation
Netherlands Organisation for Health Research and Development (ZonMw)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.zonmw.nl

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (945-14-217)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/05/2007		Yes	No
Results article	results	01/09/2013		Yes	No