A REDUCTION IN TIME WITH ELECTRONIC MONITORING IN STROKE TRIAL (ARTEMIS Trial).

Published: 12-05-2016
Last updated: 20-04-2024

to reduce the time between sounding alarm by the patient and start of intravenous thrombolysis and/ or intra-arterial trombectomy in patients with acute ischemic stroke. In a side-line study we will elucidate factors that contributed to a delay in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON46211

Source
ToetsingOnline

Brief title
ARTEMIS trial

Condition

- Central nervous system vascular disorders

Synonym
Stroke; brain infarction

Research involving
Human

Sponsors and support

Primary sponsor: Neurologie
Source(s) of monetary or material Support: Hersenstichting,ZEBRA

Intervention

Keyword: delay, IVT/IAT, stroke, treamtent

Outcome measures

Primary outcome

TSD to IAT and TSD to IVT.

Secondary outcome

- the proportion of patients finally treated with IVT /IAT calculated from:

- the total of patients for whom the ambulance issues a dispatch

- the total of patients transferred to the hospital with suspected stroke

- the total of patients with a final diagnosis of (ischemic) stroke

- functional outcome at three-months measured by telephone with the modified

Rankin scale

Study description

Background summary

For the clinical benefit of intravenous thrombolysis (IVT) or intra-arterial trombectomy (IAT) time is the most crucial factor (time=brain). Reducing the time between stroke onset en treatment is therefore a major goal. The delay from first sounding alarm and the start of treatment with IVT/IAT aslo called the *total system delay* (TSD) dependents very much on logistics and how various caregivers in this trajectory work together. A promising method to reduce the TSD is direct visual feedback to caregivers involved with the patient to encourage them to work more efficiently. In order to investigate this, however, it is important to have an accurate registration of the TSD, which is currently lacking.

Study objective

to reduce the time between sounding alarm by the patient and start of intravenous thrombolysis and/ or intra-arterial trombectomy in patients with acute ischemic stroke. In a side-line study we will elucidate factors that

contributed to a delay in calling for help by the patient or bystanders.

Study design

First we will set up an electronic and automated way of tracking the TSD. Next we will start a multiregional, multicentre prospective randomized open end-point trial to investigate if direct visual feedback to caregivers reduces the TSD.

Intervention

The intervention is not aimed at the patient but at the caregivers involved in acute stroke: direct visual feedback on the actual treatement delays for the patient they are transferring for IVT/IAT

Study burden and risks

We expect no buren or risk for the patient. The tracking device is already in use at the cardiology department of the Leiden University Medical Centre. Patients have never complaint of any inconvenience so far. The wristband they recieve up till IVT/IAT has been administred is comparable with the patient identifying wristband they receive. A formal risk assessment did not show any interference with existing medical equipment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients with suspected stroke potentially eligible for IVT and/or IAT for whom the dispatch office send out an ambulance.

Exclusion criteria

younger than 18 years

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2018
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	12-05-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	06-07-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	12-03-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT02808806

Register	ID
CCMO	NL56747.058.16