CLEOPATRA

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27029

Source
Nationaal Trial Register

Brief title
CLEOPATRA

Health condition

Acute ischemic stroke

Sponsors and support

Primary sponsor: Leading the Change (LtC); ZonMW
Source(s) of monetary or material Support: ZonMW; LeadingTheChange

Intervention

Outcome measures

Primary outcome

The distribution of outcomes on the modified Rankin scale (mRS) at three months.

Secondary outcome

- Barthel Index
- EQ5D5L

• Adverse events

Study description

Background summary

Since the publication of the first positive randomized controlled trial for endovascular treatment (EVT) patients in 2015, EVT has radically changed the outlook for stroke patients with a large vessel occlusion (LVO). LVO stroke patients can be divided into two groups. The first group consists of patients arriving early with an expected onset to groin puncture time of 6 hours or less after symptom onset (“early patients”). For early patients, EVT has become the standard of care. In this group, 38% of patients achieve functional independence. But the success of EVT puts an increasing strain on acute healthcare infrastructure, budget and personnel availability. Nevertheless, all early patients are being treated. Higher proportion of good outcome after EVT have been reported in subsequent positive trials using CT Perfusion (CTP). The second group consists of patients arriving with an expected onset to groin puncture time between 6 and 24 hours after onset (“late patients”). For late patients, success of EVT has recently been proven effective. However the CTP criteria used in these trials were strict and only 30% of late patients were considered eligible for EVT. Recent studies have shown benefit outside these selection criteria, suggesting undertreatment in this group. Since long term care for untreated patients is expensive, with annual institutional care costs surpassing 50.000€ per patient, it is clear that successful treatment in the acute phase is not only important for patients but also very beneficial for society at large.

This multicenter, observational cohort study aims to determine the cost-effectiveness CTP, compared to non-contrast CT (NCCT) and CT angiography (CTA), for the selection of patients for EVT. Acute ischemic stroke patients with an intracranial LVO (LVO) of the anterior circulation, admitted for possible EVT are included. Two subpopulations are defined: (1) “early patients” and (2) “late patients”. Data from the CLOT MR CLEAN trial, MR CLEAN registry and ongoing CONTRAST trials will be used. The primary outcome of the study will be the distribution of outcomes on the modified Rankin scale (mRS) at three months. Cost-effectiveness analysis will be performed based on cost parameters and changes in proportions of good outcomes.

Study objective

We hypothesize that by adding CTP in the workup of patients with acute ischemic stroke, the number of futile EVTs is reduced and that the outcome for patients arriving late is improved by increasing eligibility, making CTP cost-effective by improving selection for EVT.

Study design

Preparation: 6 months
Data collection: 21 months

Follow-up: 3 months
Data processing: 6 months

Intervention

The intervention is the acquisition of CTP in all patients undergoing evaluation for EVT at all intervention centers in the Netherlands. Infarct core size, penumbra size, core-penumbra mismatch and infarct location as determined by CTP will be used alone or in combination in the treatment decision model for EVT, MRPREDICTS (www.MRPREDICTS.com). With the predictive analytic model, the outcome of patients with acute ischemic stroke due to LVO will be predicted including the use of CTP data. Based on these results, the incremental cost effectiveness of CTP will be determined in a model-based analysis.

Contacts

Public
Amsterdam UMC
Ayla van Ahee

+31205666119
Scientific
Amsterdam UMC
Ayla van Ahee

+31205666119

Eligibility criteria

Inclusion criteria

• A clinical diagnosis of acute ischemic stroke.
• CT or MRI scan ruling out intracranial hemorrhage.
• Extracranial carotid and intracranial arterial occlusion demonstrated with CTP and CTA, MRA or DSA.
• Intracranial proximal arterial occlusion of the anterior circulation (intracranial carotid artery (ICA, ICA-T) or middle (M1/M2) or anterior (A1/A2) cerebral artery), demonstrated by CTA, MRA or DSA.
• Endovascular treatment was initiated; defined as groin puncture.
• Age of 18 or above.
• A score of at least 2 on the NIH Stroke Scale.

• Written informed consent.

Exclusion criteria

• Pre-stroke disability which interferes with the assessment of functional outcome at 90 days, i.e. mRS >2

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	23-07-2019
Enrollment:	1200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	19-08-2019
Application type:	First submission

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
NTR-new	NL7974
Other	METC Amsterdam UMC (location AMC) : W19_281 # 19.334

Study results