

# Prehospital triage of patients with a suspected acute stroke

Published: 22-05-2023

Last updated: 07-04-2024

The overall objective of the PRESTO-2 study is to evaluate the implementation of the Stroke Triage App, a decision support tool for individualized prehospital triage of patients with potential stroke. The specific objectives are the following: 1)...

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Central nervous system vascular disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON51821

### Source

ToetsingOnline

### Brief title

PRESTO-2

### Condition

- Central nervous system vascular disorders

### Synonym

stroke

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W, ZonMW, de Hartstichting

## Intervention

**Keyword:** Endovascular procedures, Large vessel occlusion, Prehospital triage, Stroke

## Outcome measures

### Primary outcome

Time from symptom onset to groin puncture (=start EVT) in patients with ischemic stroke who are treated with EVT

### Secondary outcome

1.

- Time from onset to needle (=start of IVT) in patients with ischemic stroke who were treated with IVT
- Percentage of patients with ischemic stroke treated with IVT within and outside the regular time window of 4.5 hours after the onset of complaints or 'last seen well'
- Percentage of patients with ischemic stroke treated with EVT within and outside the regular time window of 6 hours after the onset of symptoms or 'last seen well'
- Modified Rankin scale score after 3 months

2.

- Number and case mix of patients with ischemic stroke with and without occlusion, TIA, intracerebral haemorrhage and stroke mimic in participating hospitals (primary hospitals vs. intervention centers)
- Number and percentage of ischemic stroke patients without EVT-eligible occlusion who were taken to an intervention center and bypassed a primary

stroke center

- Number and percentage of stroke patients with EVT-eligible occlusion who were not immediately taken to an intervention center
- Compliance with Stroke Triage App advice
- Number of required acute ambulance transports (prior to reperfusion therapy)
- Number of subacute ambulance transports for transfer after reperfusion therapy or after it has become apparent that there is no indication for reperfusion therapy

## Study description

### Background summary

Every year, more than 30,000 patients with a stroke are hospitalized in the Netherlands. Treatment with intravenous alteplase (IVT) is an effective treatment for patients with ischemic stroke, but the effectiveness depends on the speed of administration. Approximately 23% of patients with acute ischemic stroke have a proximal intracranial arterial occlusion. The effect of IVT in this group of patients is small. For patients with a proximal intracranial occlusion, endovascular thrombectomy (EVT) is an effective treatment. This is a complex treatment that is only available in specialized intervention centers. Like with IVT, there is a strong time-dependent treatment effect, with treatment being more effective the earlier it is initiated. An important cause of delay is a transfer between hospitals. This occurs when patients with an intracranial occlusion are first transferred to a hospital where EVT is not possible. A transfer can be prevented by recognizing patients with a proximal intracranial occlusion in the ambulance and taking them immediately to an intervention center. This can be done through prehospital triage. To this end, prehospital stroke scores have been developed. These scores can be used to estimate the risk of an intracranial occlusion. Recently, several of these prehospital stroke scores have been prospectively validated, showing that some scores can predict the presence of an intracranial occlusion with good accuracy. Of these scores, the RACE scale shows good results in several studies. This was also the case in the PRESTO study, conducted within our ROAZ region. The RACE scale appeared to perform best of all examined prehospital scales, with an area under the receiver operating characteristic curve (AUROC) of 0.83.

Prehospital scores have now been implemented in a number of other regions in the Netherlands and beyond. The following procedure is used in these regions: when the total score of the prehospital score is higher than a defined cut-off point, the decision is made to transport patients directly to the intervention center. When the score falls below this cut-off point, the patient is transported to the nearest hospital. This method does not take into account essential regional characteristics. Previous research showed that not only the probability of having an intracranial occlusion, but also the driving times to hospitals, the workflow times of hospitals and the possible transfer times between hospitals are important factors in determining the optimal transportation strategy. We bring the aforementioned factors together in a multivariable decision model, which is made available online in the form of the Stroke Triage App for ambulance staff to determine the best transport strategy for each individual patient.

## **Study objective**

The overall objective of the PRESTO-2 study is to evaluate the implementation of the Stroke Triage App, a decision support tool for individualized prehospital triage of patients with potential stroke.

The specific objectives are the following:

- 1) Evaluation of the effectiveness of the Stroke Triage App implementation in reducing the time to EVT.
- 2) Evaluation of the consequences of the implementation of the Stroke Triage App for the number of ambulance transportations and the distribution of stroke patients across hospitals in the region.

## **Study design**

1. Before-and-after study design with difference-in-differences analysis.
2. Cohort study with simulation.

## **Intervention**

Implementation of the Stroke Triage App in the intervention region.

## **Study burden and risks**

The burden on participants is minimal. The study procedures take place in the prehospital setting and consist of a short neurological examination (2 extra items compared to current clinical practice) and transport to a hospital. There is a risk that standard treatment with intravenous thrombolysis will be minimally delayed, but the time gained to standard treatment with endovascular thrombectomy is expected to outweigh this. (For more detailed explanations and percentages, please refer to the answers to E2 (with regard to patient burden))

and to E1, E1a, E9, E9a and E12a (with regard to risk assessment)).

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Adult ( $\geq 18$  years), suspected stroke based on FAST-score  $\geq 1$ , onset of symptoms less than 12 hours ago

### Exclusion criteria

Geen

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Health services research

### Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	5000
Type:	Anticipated

### Medical products/devices used

Generic name:	Stroke Triage App
Registration:	No

## Ethics review

Not approved	
Date:	22-05-2023
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	NL82357.000.22