MR ASAP:

Multicentre Randomised trial of Acute Stroke treatment in the Ambulance with a nitroglycerin Patch

Case Report Form (CRF) ON PAPER

Version 1.1, July 2018

Study number: ___ ___ ___ ___

Inclusion date: ___ /___ /_____ DD/MM/YYYY

Please complete all forms as fully as possible.
Thank you for your cooperation.

Kind regards,

The MR ASAP team

Sophie van den Berg, Coordinating researcher

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Study number: | Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

BASELINE CRF MR ASAP

Randomisation check upon hospital admission

Inclusion criteria	
– Age 18 years or older	□ No □ Yes
– Probable diagnosis of acute stroke, as assessed by the paramedic in the prehospital setting	□ No □ Yes
– Score of 2 or 3 on the Face Arm Speech Test (FAST), as assessed by the paramedic in the prehospital setting	□ No □ Yes
– Systolic blood pressure ≥140 mm Hg, as assessed by the paramedic in the prehospital setting	□ No □ Yes
– Possibility to start trial treatment within 3 hours of symptom onset, as assessed by the paramedic in the prehospital setting	□ No □ Yes
	If any of the inclusion criteria above = No, please remove the nitroglycerin patch
Exclusion criteria	
– Considerable pre-stroke dependency in activities of daily living, defined as staying in a chronic nursing home or rehabilitation center	□ No □ Yes
– Known pregnancy or lactation	□ No □ Yes
– Indication for acute treatment with nitroglycerin or known use of nitroglycerin in the previous 12 hours	□ No □ Yes
– Indication for acute reduction of blood pressure	□ No □ Yes
– Known hypersensitivity to GTN, nitrates in general, or the adhesives used in the patch	□ No □ Yes
– Glasgow Coma Scale < 8	□ No □ Yes
– Known with any of the following heart disorders: myocardial insufficiency due to obstruction; aortic or mitral valve stenosis; constrictive pericarditis; hypertrophic obstructive cardiomyopathy; cardiac tamponade	□ No □ Yes:
Myocardial insufficiency due to obstruction;	□ No □ Yes
Aortic or mitral valve stenosis;	□ No □ Yes
Constrictive pericarditis;	□ No □ Yes
Hypertrophic obstructive cardiomyopathy;	□ No □ Yes
Cardiac tamponade	□ No □ Yes
– Known marked anaemia, defined as haemoglobin < 5 mmol/L	□ No □ Yes
– Known closed angle glaucoma	□ No □ Yes
– Known concomitant use of phosphodiesterase type-5 inhibitors (e.g. sildenafil (Viagra), tadalafil, vardenafil)	□ No □ Yes
	If any of the exclusion criteria above = Yes, please remove the nitroglycerin patch

Study number: _____ Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

Medical history/comorbidities at baseline

Medical history of:

Atrial fibrillation	□ No □ Yes
Diabetes mellitus	□ No □ Yes
Hypertension	□ No □ Yes

Medication (home) – use of:

Antiplatelet agent(s)	□ No □ Yes:
Acetylsalicylic acid/carbasalate calcium	□ No □ Yes
Clopidogrel	□ No □ Yes
Dipyridamol	□ No □ Yes
Ticagrelor	□ No □ Yes
Other:	□ No □ Yes:_____

Use of any blood pressure-lowering drug in the 3 days before randomisation	□ No □ Yes:
ACE inhibitor (*e.g. lisinopril, enalapril)*	□ No □ Yes
Angiotensin II rec antagonist (*e.g. losartan, irbesartan)*	□ No □ Yes
Beta blocker (*e.g. labetalol, metoprolol)*	□ No □ Yes
Calcium channel blocker (*e.g. amlodipine, nifedipine)*	□ No □ Yes
Diuretic (*e.g. furosemide, triamtereen)*	□ No □ Yes
Other:	□ No □ Yes:_____

Direct oral anticoagulant (DOAC)	□ No □ Yes
Therapeutic heparin *(all types, including LMWH)*	□ No □ Yes
Vitamin K antagonist	□ No □ Yes

Pre-stroke modified Rankin Scale (mRS) score

□ **0** – No symptoms
□ **1** – Minor symptoms, no limitations
□ **2** – Slight disability, no help needed
□ **3** – Moderate disability, requires some help but able to walk on assistance
□ **4** – Moderate severe disability
□ **5** – Severe disability, completely dependent

Workflow (according to the physician)

Date symptom onset: __/__/____

Witnessed symptom onset	□ No □ Yes	If No:	Time last seen well: ____:____ hh:mm
			Time symptoms noticed: ____:____ hh:mm
		If Yes:	Time stroke onset: ____:____ hh:mm
Current hospital name: _____		Time of arrival (door) current hospital: ____:____ hh:mm	
Transferred from another hospital	□ No □ Yes	If Yes: Name other hospital: _____	
Participation in other CONTRAST trial *(MR CLEAN- NO IV, -MED, -LATE or (MR) DIST*	□ No □ Yes	If Yes: Study ID number applicable trial: __ __ __ __ __	

Physical examination at baseline

Glasgow coma Scale

Eye	Motor	Verbal
□ **4** - Opens eyes spontaneously	□ **6** - Obeys commands	□ **5** - Oriented/converses normally
□ **3** - Opens eyes in response to voice	□ **5** - Localises painful stimuli	□ **4** - Confused/disoriented
□ **2** - Opens eyes in resp. to painful stimuli	□ **4** - Flexion/withdrawal to painful stimuli	□ **3** - Utters inappropriate words
□ **1** - Does not open eyes	□ **3** - Abnormal flexion to painful stimuli	□ **2** - Incomprehensible sounds
	□ **2** - Extension to painful stimuli	□ **1** - Makes no sounds
	□ **1** - Makes no movements	

Vital parameters - first intra-hospital/ER *Round numbers except for body temp (1 decimal)*

Systolic blood pressure	_____ mm Hg	Diastolic blood pressure	_____ mm Hg
Heart rate	_____ /min	Weight	_____ kg
Body temperature	__ __ . __ ^{0}C	Body temperature technique:	□ Rectal □ Tympanic

(Expected) location of the lesion

□ Left hemisphere
□ Right hemisphere
□ Posterior fossa
□ Other: _____
□ Not a TIA or stroke

Study number: _____ Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

NIHSS at baseline

1A. Level of consciousness (LOC)	1B. LOC Questions
□ **0** – Alert	□ **0** – Answers both questions correctly
□ **1** – Not alert, but arousable	□ **1** – Answers one question correctly
□ **2** – Not alert, requires repeated stimulation	□ **2** – Answers neither questions correctly
□ **3** – Comatose	
1C. LOC Commands	**2. Best gaze**
□ **0** – Performs both tasks correctly	□ **0** – Normal
□ **1** – Performs one task correctly	□ **1** – Partial gaze palsy
□ **2** – Performs neither tasks correctly	□ **2** – Forced deviation
3. Visual	**4. Facial palsy**
□ **0** – No visual loss	□ **0** – Normal
□ **1** – Partial hemianopia	□ **1** – Minor paralysis
□ **2** – Complete hemianopia	□ **2** – Partial paralysis
□ **3** – Bilateral hemianopia	□ **3** – Complete paralysis
5A. Motor left arm	**5B. Motor right arm**
□ **0** – No drift	□ **0** – No drift
□ **1** – Drift	□ **1** – Drift
□ **2** – Some effort against gravity	□ **2** – Some effort against gravity
□ **3** – No effort against gravity	□ **3** – No effort against gravity
□ **4** – No movement	□ **4** – No movement
□ **9** – Untestable, explain reason: _____	□ **9** – Untestable, explain reason: _____
6A. Motor left leg	**6B. Motor right leg**
□ **0** – No drift	□ **0** – No drift
□ **1** – Drift	□ **1** – Drift
□ **2** – Some effort against gravity	□ **2** – Some effort against gravity
□ **3** – No effort against gravity	□ **3** – No effort against gravity
□ **4** – No movement	□ **4** – No movement
□ **9** – Untestable, explain reason: _____	□ **9** – Untestable, explain reason: _____
7. Limb ataxia	**8. Sensory**
□ **0** – Absent	□ **0** – Normal
□ **1** – Present in one limb	□ **1** – Mild to moderate sensory loss
□ **2** – Present in two limbs	□ **2** – Severe or total sensory loss
9. Best language	**10. Dysarthria**
□ **0** – No aphasia (normal)	□ **0** – Normal
□ **1** – Mild to moderate aphasia	□ **1** – Mild to moderate dysarthria
□ **2** – Severe aphasia	□ **2** – Severe dysarthria
□ **3** – Mute, global aphasia	□ **9** – Intubated or other, explain: _____
11. Extinction and inattention	
□ **0** – No abnormality	
□ **1** – Inattent/extinction	
□ **2** – Profound hemi-inattention or extinction	

Laboratory results at baseline

Round numbers, except for INR, glucose, Hb (1 decimal)

CRP	_____	mg/L	INR	__ __ . __	
eGFR	__ __ __	ml/min/1.73m^2	Serum creatinine	_____	umol/L
Serum glucose	__ __ . __	mmol/L	Haemoglobin (Hb)	__ __ . __	mmol/L

Imaging results

Stroke type	□ Ischaemic stroke (a normal plain CT is compatible with ischaemic stroke) □ Intracerebral haemorrhage □ No ischaemic stroke or intracerebral haemorrhage
Other relevant finding	□ No □ Yes: _____ _____

Study number: | Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

Treatment restrictions at baseline

Any combination of these strategies is possible	
Do not resuscitate	□ No □ Yes
Do not intubate and ventilate	□ No □ Yes
Withholding other treatments that may prolong life	□ No □ Yes
Withholding food	□ No □ Yes
Withholding fluids	□ No □ Yes
Palliation with morphine or benzodiazepine	□ No □ Yes

SAE check at baseline

Did the patient experience one or more serious adverse event(s) after study inclusion?	□ No □ Yes **(if Yes, please complete SAE form(s))**

Study number: _____ Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

TREATMENT CRF MR ASAP

Nitroglycerin patch

Nitroglycerin patch administered	□ No □ Yes: **fill out below**
Date of removal nitroglycerin patch	__/__/____ DD/MM/YYYY
Time of removal nitroglycerin patch	____:____ hh:mm
Was the nitroglycerin patch removed before 24 (± 2) hours?	□ No □ Yes:
	Reason for removal: □ **0** – Other diagnosis than stroke (i.e. stroke mimic) □ **1** – Symptomatic hypotension **(fill out SAE form if serious)** □ **2** – Allergy **(fill out SAE form if serious)** □ **3** – Does not meet the eligibility criteria □ **4** – Request of patient/representative □ **5** – Other: _____

Ischaemic stroke treatment

Ischaemic stroke treatment	□ No □ Yes: **fill out below** □ N/A (no ischaemic stroke)
1) IV alteplase administered	□ No □ Yes:
Start IV alteplase (time of bolus)	____:____ hh:mm
2) Groin puncture (for IAT) performed	□ No □ Yes:
If No: Was IAT intended?	□ No □ Yes, explain why IAT was not performed while intended: _____
If Yes: Time of groin puncture (= start of IAT)	____:____ hh:mm
Final blood pressure before groin puncture	Systolic: _____ mm Hg / Diastolic: _____ mm Hg
First/primary anaesthetic management	□ **0** – None (local) □ **1** – Local with bolus short working opiates □ **2** – Moderate sedation □ **3** – Deep sedation □ **4** – General anaesthesia
Conversion of anaesthetic management	□ No □ Yes, conversion from: ____ to: ____(fill out number)
Performed intervention	□ **0** - Catheterization only (no access to target lesion) □ **1** - Cerebral DSA only (i.e. spontaneous recanalization or migration) □ **2** - Intra-arterial treatment (use of device or IA thrombolysis) □ **3** - Other (if procedure ended before thrombectomy attempt, despite target occlusion)
Please explain if '2 - IAT' was not performed:	_____
Post-intervention eTICI scored by interventionalist	□ 0 □ 1 □ 2A (<50%) □ 2B (50-<90%) □ 2C (90-99%) □ 3

Intracerebral haemorrhage treatment

Intracerebral haemorrhage treatment	□ No □ Yes: **fill out below** □ N/A (no intracerebral haemorrhage)
Early blood pressure reduction as acute treatment	□ No □ Yes
Evacuation haematoma or surgical decompression	□ No □ Yes
Other:	□ No □ Yes: _____

Blood pressure lowering drugs during hospital stay

Use of blood pressure lowering drug(s) during first 3 days (or up to discharge, if earlier)	□ No □ Yes: **fill out below**
ACE inhibitor (*e.g. lisinopril, enalapril)*	□ No □ Yes
Angiotensin II rec. antagonist (*e.g. losartan, irbesartan)*	□ No □ Yes
Beta blocker (*e.g. labetalol, metoprolol)*	□ No □ Yes
Calcium channel blocker (*e.g. amlodipine, nifedipine)*	□ No □ Yes
Diuretic (*e.g. furosemide, triamtereen)*	□ No □ Yes
Other:	□ No □ Yes: _____

Study number: | Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

CLINICAL FOLLOW-UP CRF MR ASAP

Vital signs

Date in DD/YY/MMMM; Time in hh:mm; Systolic blood pressure (SBP) and diastolic blood pressure (DBP) in mm Hg; Heart rate (HR) in seconds/min; Body temperature (BT) in degrees Celcius, 1 decimal; Body temperature technique: rectal (R) or tympanic (T)

First 24 hours after admission = day 0-1

1 hour	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
2 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
3 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
4 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
5 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
6 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
8 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
10 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
12 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
14 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
16 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
18 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
20 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
22 hours	Time: ____:____	SBP: _____	DBP: _____	HR: _____	
24 hours (day 1)	Time: ____:____	SBP: _____	DBP: _____	HR: _____	BT: __ __ . __ □ R □ T

Day 2-7 after admission +/- 4 hours (if applicable)

Day 2: 48 h – Date: __/__/____	Time: ____:____	SBP: _____	DBP: _____	HR: _____
Day 3: 72 h – Date: __/__/____	Time: ____:____	SBP: _____	DBP: _____	HR: _____
Day 4: 96 h – Date: __/__/____	Time: ____:____	SBP: _____	DBP: _____	HR: _____
Day 5: 120h – Date: __/__/____	Time: ____:____	SBP: _____	DBP: _____	HR: _____
Day 6: 144h – Date: __/__/____	Time: ____:____	SBP: _____	DBP: _____	HR: _____
Day 7: 168h – Date: __/__/____	Time: ____:____	SBP: _____	DBP: _____	HR: _____

Study number: _____ Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

NIHSS at 24 hours (+/- 4 hours)

Date of NIHSS assessment: __ /__ /____ DD/MM/YYYY

1A. Level of consciousness (LOC)
□ **0** – Alert
□ **1** – Not alert, but arousable
□ **2** – Not alert, requires repeated stimulation
□ **3** – Comatose

1B. LOC Questions
□ **0** – Answers both questions correctly
□ **1** – Answers one question correctly
□ **2** – Answers neither questions correctly

1C. LOC Commands
□ **0** – Performs both tasks correctly
□ **1** – Performs one task correctly
□ **2** – Performs neither tasks correctly

2. Best gaze
□ **0** – Normal
□ **1** – Partial gaze palsy
□ **2** – Forced deviation

3. Visual
□ **0** – No visual loss
□ **1** – Partial hemianopia
□ **2** – Complete hemianopia
□ **3** – Bilateral hemianopia

4. Facial palsy
□ **0** – Normal
□ **1** – Minor paralysis
□ **2** – Partial paralysis
□ **3** – Complete paralysis

5A. Motor left arm
□ **0** – No drift
□ **1** – Drift
□ **2** – Some effort against gravity
□ **3** – No effort against gravity
□ **4** – No movement
□ **9** – Untestable, explain reason: _____

5B. Motor right arm
□ **0** – No drift
□ **1** – Drift
□ **2** – Some effort against gravity
□ **3** – No effort against gravity
□ **4** – No movement
□ **9** – Untestable, explain reason: _____

6A. Motor left leg
□ **0** – No drift
□ **1** – Drift
□ **2** – Some effort against gravity
□ **3** – No effort against gravity
□ **4** – No movement
□ **9** – Untestable, explain reason: _____

6B. Motor right leg
□ **0** – No drift
□ **1** – Drift
□ **2** – Some effort against gravity
□ **3** – No effort against gravity
□ **4** – No movement
□ **9** – Untestable, explain reason: _____

7. Limb ataxia
□ **0** – Absent
□ **1** – Present in one limb
□ **2** – Present in two limbs

8. Sensory
□ **0** – Normal
□ **1** – Mild to moderate sensory loss
□ **2** – Severe or total sensory loss

9. Best language
□ **0** – No aphasia (normal)
□ **1** – Mild to moderate aphasia
□ **2** – Severe aphasia
□ **3** – Mute, global aphasia

10. Dysarthria
□ **0** – Normal
□ **1** – Mild to moderate dysarthria
□ **2** – Severe dysarthria
□ **9** – Intubated or other, explain:_____

11. Extinction and inattention
□ **0** – No abnormality
□ **1** – Inattent/extinction
□ **2** – Profound hemi-inattention or extinction

SAE check at 24 hours = day 1

Did the patient experience one or more serious adverse event(s)?	□ No □ Yes **(if Yes, please complete SAE form(s))**

Study number: | Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

Treatment restrictions after baseline: day 1-7 (+/- 4 hours)

Day 1-7, or until discharge, if earlier. Any combination of these strategies is possible.

Day 1: 24h	
Treatment restrictions changed after baseline, on day 1?	□ No □ Yes: **fill out below**
Do not resuscitate	□ No □ Yes
Do not intubate and ventilate	□ No □ Yes
Withholding other treatments that may prolong life	□ No □ Yes
Withholding food	□ No □ Yes
Withholding fluids	□ No □ Yes
Palliation with morphine or benzodiazepine	□ No □ Yes
Day 2: 48h	
Treatment restrictions changed (again) on day 2?	□ No □ Yes: **fill out below**
Do not resuscitate	□ No □ Yes
Do not intubate and ventilate	□ No □ Yes
Withholding other treatments that may prolong life	□ No □ Yes
Withholding food	□ No □ Yes
Withholding fluids	□ No □ Yes
Palliation with morphine or benzodiazepine	□ No □ Yes
Day 3: 72h	
Treatment restrictions changed (again) on day 3?	□ No □ Yes: **fill out below**
Do not resuscitate	□ No □ Yes
Do not intubate and ventilate	□ No □ Yes
Withholding other treatments that may prolong life	□ No □ Yes
Withholding food	□ No □ Yes
Withholding fluids	□ No □ Yes
Palliation with morphine or benzodiazepine	□ No □ Yes
Day 4: 96h	
Treatment restrictions changed (again) on day 4?	□ No □ Yes: **fill out below**
Do not resuscitate	□ No □ Yes
Do not intubate and ventilate	□ No □ Yes
Withholding other treatments that may prolong life	□ No □ Yes
Withholding food	□ No □ Yes
Withholding fluids	□ No □ Yes
Palliation with morphine or benzodiazepine	□ No □ Yes
Day 5: 120h	
Treatment restrictions changed (again) on day 5?	□ No □ Yes: **fill out below**
Do not resuscitate	□ No □ Yes
Do not intubate and ventilate	□ No □ Yes
Withholding other treatments that may prolong life	□ No □ Yes
Withholding food	□ No □ Yes
Withholding fluids	□ No □ Yes
Palliation with morphine or benzodiazepine	□ No □ Yes
Day 6: 144h	
Treatment restrictions changed (again) on day 6?	□ No □ Yes: **fill out below**
Do not resuscitate	□ No □ Yes
Do not intubate and ventilate	□ No □ Yes
Withholding other treatments that may prolong life	□ No □ Yes
Withholding food	□ No □ Yes
Withholding fluids	□ No □ Yes
Palliation with morphine or benzodiazepine	□ No □ Yes
Day 7: 168 hours	
Treatment restrictions changed (again) on day 7?	□ No □ Yes: **fill out below**
Do not resuscitate	□ No □ Yes
Do not intubate and ventilate	□ No □ Yes
Withholding other treatments that may prolong life	□ No □ Yes
Withholding food	□ No □ Yes
Withholding fluids	□ No □ Yes
Palliation with morphine or benzodiazepine	□ No □ Yes

Study number: | Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

Modified Rankin Scale (mRS) score: day 7 (+/- 1 day) or at discharge, if earlier

Date of mRS assessment: __ /__ /____ DD/MM/YYYY

mRS score

□ **0** – No symptoms
□ **1** – Minor symptoms, no limitations
□ **2** – Slight disability, no help needed
□ **3** – Moderate disability, requires some help but able to walk on assistance
□ **4** – Moderate severe disability
□ **5** – Severe disability, completely dependent
□ **6** – Death **(fill out SAE form)**

SAE check at 2-7 days

Did the patient experience one or more serious adverse event(s)?	□ No □ Yes **(if Yes, please complete SAE form(s))**

Study number: | Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

Discharge

Date of discharge (dead or alive)		
Was the patient discharged	□ No □ Yes:	Date of discharge (dead or alive): ___/___/_____ DD/MM/YYYY
Final diagnosis		
Choose final diagnosis		□ **0** – Ischaemic stroke □ **1** – TIA □ **2** – Intracerebral haemorrhage □ **3** – Other: _____
Cause of ischaemic stroke/TIA according to TOAST criteria		□ **0** – Large artery atherosclerosis □ **1** – Cardioembolism □ **2** – Small vessel occlusion (lacunar) □ **3** – Other determined aetiology: _____ □ **4** – Undertermined aetiology
Interventions during hospital stay		
Hypotension requiring clinical intervention		□ No □ Yes **(fill out SAE form if serious)**
Hypertension requiring clinical intervention		□ No □ Yes **(fill out SAE form if serious)**
Decompressive hemicraniectomy for ischaemic stroke performed		□ No □ Yes **(fill out SAE form)** □ N/A (no ischaemic stroke)

N/A = not applicable

SAE check at discharge

Did the patient experience one or more serious adverse event(s) during hospital stay?	□ No □ Yes **(if Yes, please complete SAE form(s))**

Study number: _____ Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

SERIOUS ADVERSE EVENT (SAE) CRF

General information

Name investigator: _____ Signature investigator:

Date of SAE report: ____/____/_____ DD/MM/YYYY

Description of SAE (in English or Dutch):

_____
_____
_____
_____
_____
_____
_____
_____

Date of SAE onset

Date: ____/____/_____ DD/MM/YYYY

Neurological deterioration and/or neuroimaging

Neurological deterioration of 4 points or more on NIHSS?	□ No	□ Yes
Neurological deterioration of 2 points or more on **one NIHSS Item**?	□ No	□ Yes
Was there neuroimaging performed for this SAE/Neurological deterioration?	□ No	□ Yes

Serious Adverse Event **category**, please choose one:

□ **0** – Results in death
□ **1** – Life threatening (at the time of event)
□ **2** – Requires or prolongs hospitalisation
□ **3** – Results in persistent or significant disability or incapacity
□ **4** – Other, please specify: _____

SAE **expected**?

An SAE is 'expected' if this is one of the known side effects of the study medication or one of the common (potentially) serious complications after stroke as listed in the appendices of the study protocol.
If No: please report the unexpected SAE within 24 hours to mrasap@amc.nl

□ No □ Yes

Select **most likely cause of** SAE, please choose one:

□ **0** – Stroke progression
□ **1** – New ischaemic stroke:
□ Same □ Different vascular territory
□ **2** – Intracranial haemorrhage
□ **3** – Extracranial haemorrhage
□ **4** – Cardiac ischaemia
□ **5** – Allergic reaction
□ **6** – Pneumonia
□ **7** – Other infection, please specify: _____
□ **8** – Hypotension requiring clinical intervention
□ **9** – Hypertension requiring clinical intervention
□ **10** – Other, please specify: _____

Was there **another cause** of (S)AE, you may choose multiple

□ No □ Yes:
□ **0** – Stroke progression
□ **1** – New ischaemic stroke:
□ Same □ Different vascular territory
□ **2** – Intracranial haemorrhage
□ **3** – Extracranial haemorrhage
□ **4** – Cardiac ischaemia
□ **5** – Allergic reaction
□ **6** – Pneumonia
□ **7** – Other infection: _____
□ **8** – Hypotension requiring clinical intervention
□ **9** – Hypertension requiring clinical intervention
□ **10** – Other, please specify:_____

Relationship with the study treatment

□ **0** – None
□ **1** – Unlikely
□ **2** – Possible
□ **3** – Probable
□ **4** – Definite

Actions regarding the study treatment:

□ **0** – None
□ **1** – Interrupted
□ **2** – Discontinued
□ **3** – Other, please specify:_____

Outcome

□ **0** – Resolved without sequela(e) date: __ /__ /____ DD/MM/YYYY
□ **1** – Resolved with sequela(e) date: __ /__ /____ DD/MM/YYYY and describe sequela(e): _____
_____
□ **2** – Ongoing (pending)
□ **3** – Death date: __ /__ /____ DD/MM/YYYY

Additional SAE forms are available on the website: https://mrasap.nl/documents.html

Study number: _____ Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

Wat is een SAE?

SAE is de afkorting van Serious Adverse Event. Een SAE is een ongewenst medisch voorval bij een patiënt of proefpersoon dat niet noodzakelijk een oorzakelijk verband heeft met de behandeling en dat:

- *dodelijk is, en/of*
- *levensgevaar oplevert voor de proefpersoon, en/of*
- *opname in een ziekenhuis of verlenging van de opname noodzakelijk maakt, en/of*
- *blijvende of significante invaliditeit of arbeidsongeschiktheid veroorzaakt, en/of*
- *zich uit in een aangeboren afwijking of misvorming*

Een patiënt kan meerdere SAE's hebben gedurende de follow-up periode van 3 maanden. Het terugplaatsen van een botlap is een SAE, omdat de patiënt opnieuw moet worden opgenomen in het ziekenhuis. Mocht de patiënt een verkeersongeluk krijgen en moeten worden opgenomen vanwege een operatie van bijvoorbeeld de heup, dan is het wederom een SAE. De dood is per definitie een SAE, ook al is de doodsoorzaak niet gerelateerd aan de studie/het infarct. Hieronder geven we enkele voorbeelden van SAE's.

Study number: _____ Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

SERIOUS ADVERSE EVENT (SAE) CRF

SAE number: 1/2/3/4/5/6/7/8/9/10

General information

Name investigator: dr. X Signature investigator:

Date of report: 08 / 10 / 2018 DD/MM/YYYY

Description of SAE (in Dutch or English):

75-year-old male with right-sided hemiparalysis and aphasia due to intracerebral haemorrhage was allocated to transdermal nitroglycerin treatment. During hospital stay, he developed a fever (T39.4°C). Laboratory results showed an increased CRP level. X-thorax showed signs of infiltration. Antibiotic therapy was started.

Date of SAE onset

04 / 10 / 2018 DD/MM/YYYY

Neurological deterioration and/or neuroimaging

Neurological deterioration of 4 points or more on NIHSS?	X No ☐ Yes
Neurological deterioration of 2 points or more on **one NIHSS Item**?	X No ☐ Yes
Was there neuroimaging performed for this SAE/Neurological deterioration?	X No ☐ Yes

Serious Adverse Event **category**, please choose one:

☐ **0** – Results in death
☐ **1** – Life threatening (at the time of event)
X **2** – Requires or prolongs hospitalisation
☐ **3** – Results in persistent or significant disability or incapacity
☐ **4** – Other, please specify: _____

SAE **expected**?

An SAE is "expected" if this is one of the known side effects of the study medication or one of the common (potentially) serious complications after stroke as listed in appendices 8 and 9 of the study protocol.
If No: please report the unexpected SAE within 24 hours to mrasap@amc.nl

☐ No X Yes

Select **cause** of SAE, please choose one:

☐ **0** – Stroke progression
☐ **1** – New ischaemic stroke:
☐ Same ☐ Different vascular territory
☐ **2** – Intracranial haemorrhage
☐ **3** – Extracranial haemorrhage
☐ **4** – Cardiac ischaemia
☐ **5** – Allergic reaction
X **6** – Pneumonia
☐ **7** – Other infection, please specify: _____
☐ **8** – Hypotension requiring clinical intervention
☐ **9** – Hypertension requiring clinical intervention
☐ **10** – Other, please specify: _____

Was there **another cause** of (S)AE, you may choose multiple

X No ☐ Yes:
☐ **0** – Stroke progression
☐ **1** – New ischaemic stroke:
☐ Same ☐ Different vascular territory
☐ **2** – Intracranial haemorrhage
☐ **3** – Extracranial haemorrhage
☐ **4** – Cardiac ischaemia
☐ **5** – Allergic reaction
☐ **6** – Pneumonia
☐ **7** – Other infection: _____
☐ **8** – Hypotension requiring clinical intervention
☐ **9** – Hypertension requiring clinical intervention
☐ **10** – Other, please specify: _____

Relationship with the study treatment

X **0** – None
☐ **1** – Unlikely
☐ **2** – Possible
☐ **3** – Probable
☐ **4** – Definite

Actions regarding the study treatment:

X **0** – None
☐ **1** – Interrupted
☐ **2** – Discontinued
☐ **3** – Other, please specify: _____

Outcome

☐ **0** – Resolved without sequela(e) date: __/__/____ DD/MM/YYYY
☐ **1** – Resolved with sequela(e) date: __/__/____ DD/MM/YYYY and describe sequela(e): _____
X **2** – Ongoing (pending) _____
☐ **3** – Death date: __/__/____ DD/MM/YYYY

MR ASAP CONTRAST

Study number: _____ Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

SERIOUS ADVERSE EVENT (SAE) CRF

SAE number: 1/**2**/3/4/5/6/7/8/9/10

General information

Name investigator: dr. X Signature investigator:

Date of report: 07 / 04 / 2019 DD/MM/YYYY

Description of SAE (in Dutch or English):

50-year-old female with left-sided hemiparesis and facial palsy due to ischaemic stroke. Treatment arm: control (no nitroglycerin patch). The patient experienced clinical deterioration (increase NIHSS > 4 points) on day 1. CT-cerebrum revealed a midline shift, increase of edema, and expansion of infarcted territory. A decompressive hemicraniectomy was performed. Surgery was without complications.

Date of SAE onset

02 / 04 / 2019 DD/MM/YYYY

Neurological deterioration and/or neuroimaging

Neurological deterioration of 4 points or more on NIHSS?	☐ No X Yes
Neurological deterioration of 2 points or more on **one NIHSS Item**?	☐ No X Yes
Was there neuroimaging performed for this SAE/Neurological deterioration?	☐ No X Yes

Serious Adverse Event **category**, please choose one:

☐ **0** – Results in death
X **1** – Life threatening (at the time of event)
☐ **2** – Requires or prolongs hospitalisation
☐ **3** – Results in persistent or significant disability or incapacity
☐ **4** – Other, please specify: _____

SAE **expected**?

An SAE is "expected" if this is one of the known side effects of the study medication or one of the common (potentially) serious complications after stroke as listed in appendices 8 and 9 of the study protocol.
If No: please report the unexpected SAE within 24 hours to mrasap@amc.nl

☐ No X Yes

Select **cause** of SAE, please choose one:

X **0** – Stroke progression
☐ **1** – New ischaemic stroke:
☐ Same ☐ Different vascular territory
☐ **2** – Intracranial haemorrhage
☐ **3** – Extracranial haemorrhage
☐ **4** – Cardiac ischaemia
☐ **5** – Allergic reaction
☐ **6** – Pneumonia
☐ **7** – Other infection, please specify: _____
☐ **8** – Hypotension requiring clinical intervention
☐ **9** – Hypertension requiring clinical intervention
☐ **10** – Other, please specify: _____

Was there **another cause** of (S)AE, you may choose multiple

X No ☐ Yes:
☐ **0** – Stroke progression
☐ **1** – New ischaemic stroke:
☐ Same ☐ Different vascular territory
☐ **2** – Intracranial haemorrhage
☐ **3** – Extracranial haemorrhage
☐ **4** – Cardiac ischaemia
☐ **5** – Allergic reaction
☐ **6** – Pneumonia
☐ **7** – Other infection: _____
☐ **8** – Hypotension requiring clinical intervention
☐ **9** – Hypertension requiring clinical intervention
☐ **10** – Other, please specify: _____

Relationship with the study treatment

X **0** – None
☐ **1** – Unlikely
☐ **2** – Possible
☐ **3** – Probable
☐ **4** – Definite

Actions regarding the study treatment:

X **0** – None
☐ **1** – Interrupted
☐ **2** – Discontinued
☐ **3** – Other, please specify: _____

Outcome

☐ **0** – Resolved without sequela(e) date: __/__/____ DD/MM/YYYY
☐ **1** – Resolved with sequela(e) date: __/__/____ DD/MM/YYYY and describe sequela(e): _____
X **2** – Ongoing (pending) _____
☐ **3** – Death date: __/__/____ DD/MM/YYYY

MR ASAP CONTRAST