DATA COLLECTION FORMS PARTICIPATING SITES

VISIT 1: BASELINE

Inclusion criteria known at time of randomisation		**Yes**	**No**
1.	The patient received rt-PA thrombolysis treatment for an ischemic stroke	☐	☐
2.	The patient is aged ≥ 18 years	☐	☐
3.	Written informed consent is obtained	☐	☐

Exclusion criteria known at time of randomisation		**Yes**	**No**
1.	Known antiplatelet therapy in the previous 5 days (in case of uncertainty the patient may be included)	☐	☐
2.	Known thrombocytopenia (thrombocyte count ≤ 100 * 10E9/l	☐	☐
3.	Contra-indication for aspirin	☐	☐
4.	Known anticoagulant therapy in the previous 5 days	☐	☐
5.	Known legal incompetence of the patient prior to stroke	☐	☐

Demography

Date of birth: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Sex:
☐ Male
☐ Female

Ethnicity:
☐ White (e.g. European, North African)
☐ Black (e.g. African, African-American)
☐ Hindu (Surinaams-Hindoestaans)
☐ Chinese
☐ Other
☐ Unknown

Medical history		**Yes**	**No**
1.	Cerebral ischemia (TIA or infarction)	☐	☐
2.	Intracerebral haemorrhage	☐	☐
3.	Hypertension	☐	☐
4.	Diabetes Mellitus	☐	☐
5.	Hypercholesterolemia	☐	☐
6.	Ischemic heart disease	☐	☐
7.	Peripheral arterial disease	☐	☐
8.	Coagulation disorder	☐	☐

Relevant medication		**Yes**	**No**
1.	**Dihydropyridinen Calciumantagonists:** Amlodipine (Norvasc) Barnidipine (Cyress) Felodipine (Plendil) Isradipine (Lomir) Iacidipine (Motens) Iercanidipine (Lerdip) Nicardipine (Cardene) Nifedipine (Adalat) Nimodipine (Nimotop) Nitrendipine (Baypress)	☐	☐
2.	**Insulin**	☐	☐
3.	**Statin**	☐	☐
4.	**Anticoagulant therapy** (unknown at time of randomisation) Acenocoumarol (Sintrom) Fenprocoumon (Marcoumar)	☐	☐
5.	**Antiplatelet therapy** (unknown at time of randomisation): Acetylsalicylic Acid (Aspirine) Carbasalatecalcium (Ascal) Dipyridamole (Persantin) Clopidogrel (Plavix)	☐	☐

Modified Rankin Scale score *prior* to stroke

Any disability at all prior to stroke (let op: dus vóór beroerte) |__| Yes |__| No

If yes, only one of the following applies, choose one

1. No significant disability despite symptoms; able to carry out all usual duties and activities ☐
2. Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance ☐
3. Moderate disability; requiring some help, but able to walk without assistance ☐
4. Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance ☐
5. Severe disability; bedridden, incontinent and requiring constant nursing care and attention ☐

Vital signs: blood pressure (mmHg)

Systolic |__|__|__| mmHg

Diastolic |__|__|__| mmHg

Physical examination at baseline

Glasgow Coma Scale:

Eye opening (E) |__|
1 = none
2 = to pain
3 = to speech
4 = spontaneous

Motor response (M) |__|
1 = none
2 = extension
3 = flexor response
4 = withdrawal
5 = localizes pain
6 = obeys commands

Verbal response (V) |__|
1 = none
2 = incomprehensible
3 = inappropriate
4 = confused
5 = oriented
A = aphasia
T = intubated

NIH-Stroke Scale at baseline. Every item must be scored			
1a.	Level of consciousness (LOC)	0 = Alert, keenly responsive 1 = Not alert, but arousable by minor stimulation 2 = Not alert, requires repeated stimulation to attend 3 = No response, other then reflexive posturing	__
1b.	LOC questions	0 = Answers both questions correctly 1 = Answers one question correctly 2 = Answers neither question correctly	__
1c.	LOC commands	0 = Performs both tasks correctly 1 = Performs one task correctly 2 = Performs neither task correctly	__

2.	Best gaze	0 = Normal 1 = Partial gaze palsy 2 = Forced deviation	__
3.	Visual fields	0 = No visual loss 1 = Partial hemianopia 2 = Complete hemianopia 3 = Bilateral hemianopia (including (cortical) blindness)	__
4.	Facial palsy	0 = Normal symmetrical movements 1 = Minor paralysis (flattened nasolabial fold) 2 = Partial paralysis (total lower face paralysis) 3 = Complete paralysis (upper and lower face)	__
5.	Motor arm	0 = No drift 1 = Drift, drifts down before full 10 sec, does not hit bed 2 = Some effort against gravity, hits bed before 10 sec 3 = No effort against gravity, arm falls 4 = No movement UN = Amputation or joint fusion	L __ R __
6.	Motor leg	0 = No drift 1 = Drift, drifts down before full 5 sec, does not hit bed 2 = Some effort against gravity, hits bed before 5 sec 3 = No effort against gravity, leg falls 4 = No movement UN = Amputation or joint fusion	L __ R __
7.	Limb ataxia	0 = Absent 1 = Present in one limb 2 = Present in two limbs UN = Amputation or joint fusion	__
8.	Sensory	0 = Normal 1 = Mild-to-moderate sensory loss 2 = Severe to total sensory loss	__
9.	Best language	0 = 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 UN = Intubated, other physical barrier	__
11.	Extinction and inattention	0 = No abnormality 1 = Visual, tactile, auditory, spatial or personal inattention 2 = Profound hemi-inattention or more modalities	__
	Total score		__

Radiology

Head CT-scan

Performed: Yes |__| No |__|

All CT-scans will be evaluated blindly at the coordinating center.

→ Please send a CD-Rom with all head CT-scans to:

Academisch Medisch Centrum
Klinisch OnderzoeksBureau Neurologie
Locatie H2-233
Postbus 22660
1100 DD Amsterdam

Laboratory tests at baseline

Platelet count: |__|__|__| x10E9/L Not available |__|

INR: |__|.|__|__| Not available |__|

Time frame symptom onset and rt-PA treatment

Date of symptom onset |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Time of symptom onset |__|__|:|__|__|
H r min

Date of rt-PA bolus administration |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Time of rt-PA administration |__|__|:|__|__|
H r min

Randomisation

Treatment allocation (ALEA) : |__| Aspégic 300mg |__| No Aspégic

Did patient receive Aspégic 300mg iv? |__| Yes |__| No

Date of Aspégic administration: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Time of Aspégic administration: |__|__|:|__|__|
H r min

VISIT 2: early follow-up (7 – 10 days or at discharge if discharge < 7 days)

Date of examination: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

NIH Stroke Scale Score at 7-10 days. Every item must be scored!			
1a.	Level of consciousness (LOC)	0 = Alert, keenly responsive 1 = Not alert, but arousable by minor stimulation 2 = Not alert, requires repeated stimulation to attend 3 = No response, other then reflexive posturing	__
1b.	LOC questions	0 = Answers both questions correctly 1 = Answers one question correctly 2 = Answers neither question correctly	__
1c.	LOC commands	0 = Performs both tasks correctly 1 = Performs one task correctly 2 = Performs neither task correctly	__
2.	Best gaze	0 = Normal 1 = Partial gaze palsy 2 = Forced deviation	__
3.	Visual fields	0 = No visual loss 1 = Partial hemianopia 2 = Complete hemianopia 3 = Bilateral hemianopia (including (cortical) blindness)	__
4.	Facial palsy	0 = Normal symmetrical movements 1 = Minor paralysis (flattened nasolabial fold) 2 = Partial paralysis (total lower face paralysis) 3 = Complete paralysis (upper and lower face)	__
5.	Motor arm	0 = No drift 1 = Drift, drifts down before full 10 sec, does not hit bed 2 = Some effort against gravity, hits bed before 10 sec 3 = No effort against gravity, arm falls 4 = No movement UN = Amputation or joint fusion	L __ R __
6.	Motor leg	0 = No drift 1 = Drift, drifts down before full 5 sec, does not hit bed 2 = Some effort against gravity, hits bed before 5 sec 3 = No effort against gravity, leg falls 4 = No movement UN = Amputation or joint fusion	L __ R __
7.	Limb ataxia	0 = Absent 1 = Present in one limb 2 = Present in two limbs UN = Amputation or joint fusion	__

8.	Sensory	0 = Normal 1 = Mild-to-moderate sensory loss 2 = Severe to total sensory loss	__
9.	Best language	0 = 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 UN = Intubated, other physical barrier	__
11.	Extinction and inattention	0 = No abnormality 1 = Visual, tactile, auditory, spatial or personal inattention 2 = Profound hemi-inattention or more modalities	__
	Total score		__

Visit 3: Discharge

Date of discharge: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Destination after discharge:

- ☐ Home
- ☐ Rehabilitation facility
  *please specify name: essential for follow-up*_____
- ☐ Nursing home
  *please specify name: essential for follow-up*_____
- ☐ Other hospital
  *please specify name: essential for follow-up*_____
- ☐ Patient has died
- ☐ Unknown

Were there episodes of clinical deterioration or any other (serious) adverse events - including death - during admission? Yes |__| No |__| *If yes please fill out the "(serious) adverse event form"*

Statement local investigator

Hereby I declare that the pages of Visit 1 - 3 have been checked for completeness and accuracy.

Name researcher: _____

Signature researcher: _____

Date: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Please enter data in Oracle Database at https://oc.amc.nl/artis/index.htm OR send copy or fax completed CRF to: Academisch Medisch Centrum KOB Neurologie, H2-233 , Postbus 22660, 1100 DD Amsterdam, faxnummer: 020-5669290

(SERIOUS) ADVERSE EVENTS FORMS PARTICIPATING SITES

(SERIOUS) ADVERSE EVENT FORM

Investigator identification

Name: _____

Centre: _____

Phone number: _____

Date of (S)AE: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Time of (S)AE: |__|__|:|__|__| Unknown |__|
H r min

Is the AE one or more of the following:

1. CT-documented haemorrhage with↑NIHSS score ≥ 4 compared to best NIHSS since admission Yes |__| No |__|

2. potentially life-threatening systemic bleeding which requires immediate medical intervention Yes |__| No |__|

3. death Yes |__| No |__|

4. other life threatening situation (at time of event) Yes |__| No |__|

5. AE leading to prolonged hospitalisation Yes |__| No |__|

6. AE leading to persistent or significant disability Yes |__| No |__|

If any answer is yes, this is a serious adverse event (SAE)

If SAE, please enter data < 24 hours in Oracle Database at https://oc.amc.nl/artis/index.htm or send e-mail to artis@amc.nl and fax (serious) adverse event form to: 020-5669290

Physical examination

Glasgow Coma Scale
Last recorded GCS score **before** (S)AE:

Glasgow Coma Scale: Eye opening (E) |__| Motor response (M) |__| Verbal response (V) |__|

Eye opening (E)	Motor response (M)	Verbal response (V)
1 = none	1 = none	1 = none
2 = to pain	2 = extension	2 = incomprehensible
3 = to speech	3 = flexor response	3 = inappropriate
4 = spontaneous	4 = withdrawal	4 = confused
	5 = localizes pain	5 = oriented
	6 = obeys commands	A = aphasia
		T = intubated

GCS score **at the time of** (S)AE:

Glasgow Coma Scale: Eye opening (E) |__| Motor response (M) |__| Verbal response (V) |__|

Eye opening (E)	Motor response (M)	Verbal response (V)
1 = none	1 = none	1 = none
2 = to pain	2 = extension	2 = incomprehensible
3 = to speech	3 = flexor response	3 = inappropriate
4 = spontaneous	4 = withdrawal	4 = confused
	5 = localizes pain	5 = oriented
	6 = obeys commands	A = aphasia
		T = intubated

National Institutes of Health Stroke Scale (NIHSS)

What is the NIHSS score increase **at the time of** the (S)AE ?

- ☐ < 2 points
- ☐ ≥ 2 points but < 4 points
- ☐ ≥ 4 points

Radiology

Head CT-scan

Performed: Yes |__| No |__|

All CT-scans will be evaluated blindly at the coordinating center.

→ Please send a CD-Rom with all head CT-scans to:

Academisch Medisch Centrum
Klinisch OnderzoeksBureau Neurologie
H2-233, tnv Y. Roos
Postbus 22660
1100 DD Amsterdam

(Serious) Adverse Event Number: |__|__|

Severity

Severity of (S)AE:
- ☐ mild
- ☐ moderate
- ☐ severe

Presumed cause of (S)AE

Presumed predominant cause of (S)AE **(choose one)**

Haemorrhage
- ☐ Any haemorrhagic transformation in infarct region
- ☐ Any intracerebral haemorrhage in other region
- ☐ Any systemic haemorrhage, please specify location .....

Thrombo-embolic
- ☐ Progressive ischemic stroke
- ☐ New infarction in region of initial stroke
- ☐ New infarction in other region

Other possible causes
- ☐ Allergic reaction
- ☐ Pneumonia
- ☐ Urine tract infection
- ☐ Epileptic seizure
- ☐ Other: .....

(S)AE related to the Aspégic treatment:

- ☐ Not applicable (patient randomised for standard care)
- ☐ Unlikely
- ☐ Possible
- ☐ Probably
- ☐ Definite

Treatment

Did the (S)AE require intervention? Yes |__| No |__|

If yes, please specify: .....

Outcome

If outcome is unknown at this moment, please continue this (Serious) Adverse Event form and fill in later

Outcome after (S)AE:

- ☐ recovered
- ☐ recovering
- ☐ recovered with sequelae
- ☐ not recovered
- ☐ fatal

Date of this outcome |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Statement local investigator

Hereby I declare that the pages of facultative form (Serious) Adverse Event have been checked for completeness and accuracy.

Name researcher: _____

Signature researcher: _____

Date: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

SAE notification should be within 24 hours
Please enter data in Oracle Database at https://oc.amc.nl/artis/index.htm OR
send copy or fax completed (S)AE form to: Academisch Medisch Centrum
H2-233 Klinisch OnderzoeksBureau, Postbus 22660, 1100 DD Amsterdam, fax: 020-5669290

DATA COLLECTION FORMS COORDINATING CENTER (FOLLOW-UP & RADIOLOGY)

THREE MONTHS FOLLOW-UP

Follow-up interview performed: Yes |__| No |__|

If no, why not:
- ☐ patient (or relative / caregiver) cannot be reached (lost to follow-up)
- ☐ patient refuses
- ☐ patient has deceased

If yes, the person interviewed was:
- ☐ patient
- ☐ relative / caregiver

Date of interview |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Modified Rankin Scale score

Did the patient have any symptoms left Yes |__| No |__|

If yes, tick one of the boxes below; only one answer possible.

1. No significant disability despite symptoms; able to carry out all usual duties and activities ☐
2. Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance ☐
3. Moderate disability; requiring some help, but able to walk without assistance ☐
4. Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance ☐
5. Severe disability; bedridden, incontinent and requiring constant nursing care and attention ☐
6. Dead ☐

Comments: .....

.....

.....

AMC Linear Disability Scale score

	ALDS Are you able to…	yes	yes with difficulty	no	un-known
1	…ride a bike for at least 2 hours?	☐	☐	☐	☐
2	...carry a shopping bag upstairs?	☐	☐	☐	☐
3	…fetch groseries for 3-4 days?	☐	☐	☐	☐
4	…travel by local bus or tram?	☐	☐	☐	☐
5	...walk for more than 15 minutes?	☐	☐	☐	☐
6	…carry a tray?	☐	☐	☐	☐
7	…to go shopping for clothes?	☐	☐	☐	☐
8	…cut your toe nails?	☐	☐	☐	☐
9	…go to a party?	☐	☐	☐	☐
10	…hang out and take in a load for washing?	☐	☐	☐	☐
11	…vacuum without moving any furniture?	☐	☐	☐	☐
12	…move a bed or a table?	☐	☐	☐	☐
13	….reach into a high cupboard?	☐	☐	☐	☐
14	…walk up a flight of stairs?	☐	☐	☐	☐
15	…write a letter?	☐	☐	☐	☐
16	….cross the road?	☐	☐	☐	☐
17	…have a shower and wash your hair?	☐	☐	☐	☐
18	…put on and take off lace-up shoes?	☐	☐	☐	☐
19	…cut your finger nails?	☐	☐	☐	☐
20	…pick something up from the floor?	☐	☐	☐	☐
21	…read a newspaper?	☐	☐	☐	☐
22	…clear the table after a meal?	☐	☐	☐	☐
23	…peel and core an apple?	☐	☐	☐	☐
24	…prepare breakfast or lunch?	☐	☐	☐	☐
25	…eat a meal at the table?	☐	☐	☐	☐

	ALDS	yes	yes with difficulty	no	un-known
26	…put on/take off socks and slip on shoes?	☐	☐	☐	☐
27	…sit up (from lying) in bed?	☐	☐	☐	☐
28	…answer the telephone?	☐	☐	☐	☐
29	…make coffee or tea?	☐	☐	☐	☐
30	…pul long trousers on?	☐	☐	☐	☐
31	…si ton the edge of a bed from lying down?	☐	☐	☐	☐
32	…wash and dry your lower body?	☐	☐	☐	☐
33	…wash and dry your face and hands?	☐	☐	☐	☐
34	…go to the toilet?	☐	☐	☐	☐
35	…put on and take off a T-shirt?	☐	☐	☐	☐

Was treatment allocation recalled?

☐ Yes, Aspégic treatment

☐ Yes, standard treatment

☐ No

Statement investigator coordinating centre

Hereby I declare that the pages of 3 months follow-up have been checked for completeness and accuracy.

Name researcher: _____

Signature researcher: _____

Date: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

RADIOLOGY

Baseline head CT-scan

Date of radiology report: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Affected brain side: Left |__| Right |__| Not determined |__|

Any early ischemic changes (EIC) present? Yes |__| No |__|

If EIC, please location: Left |__| Right |__|
Supratentorial |__| Infratentorial |__|

ASPECTS-score: 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐

Estimated volume of EIC in MCA territory > 1/3? Yes |__| No |__|

Marked hyperdense middle cerebral artery sign: Left |__| Right |__| No |__|

Degree of periventricular leukoariosis:

- ☐ no signs of leukoariosis
- ☐ moderate leukoariosis
- ☐ severe leukoariosis

FOLLOW UP head CT-scan

Follow up head CT-scan performed? Yes |__| No |__|

Date of radiology report: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Date of performing head CT-scan: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y

Time of head CT-scan: |__|__|:|__|__|
H r min

Indication for head CT-scan (choose one)
- ☐ Clinical deterioration < 4 points on NIHSS
- ☐ Clincal deterioration ≥ 4 points on NIHSS
- ☐ Unknown
- ☐ Other *(please specify)* _____

CT-findings (one or more of the following):
- ☐ Unchanged compared to baseline head CT-scan
- ☐ Marked hyperdense middle cerebral artery sign
- ☐ Increase in parenchymal hypoattenuation
- ☐ Increase in ischemic edema *without* mass effect
- ☐ Increase in ischemic edema *with* mass effect
- ☐ Intracerebral hemorrhage (ICH)
- ☐ Unknown
- ☐ Other *(please specify)*_____

If ICH, please specify type of hemorrhage (choose one)
- ☐ Hemorrhagic infarction type 1
- ☐ Hemorrhagic infarction type 2
- ☐ Parenchymal infarction type 1
- ☐ Parenchymal infarction type 2
- ☐ Remote primary intracerebral hemorrhage type 1
- ☐ Remote primary intracerebral hemorrhage type 2

Do the radiological findings explain the clinical deterioration?

Yes |__| No |__| Uncertain |__| Not applicable |__|

Statement investigator coordinating centre

Hereby I declare that the pages of radiology have been checked for completeness and accuracy.

Name researcher: _____

Signature researcher: _____

Date: |__|__| |__|__|__| |__|__|__|__|
d d m m m y y y y