



Sociedad Iberoamericana  
de Enfermedad Cerebrovascular



## SIECV-SITS Stroke registry

### Patient Identification Form

*(For internal use only. This information is not to be included in the CRF)*

#### 1.1 Patient information

First name of patient		
Family name of patient		
Date of birth	DD-MM-YYYY	
Social Security No/Unique personal ID		
Gender	Male <input type="checkbox"/>	Female <input type="checkbox"/>
Phone number to patient		
Mobile number to patient		
Contact person for patient	Name	Phone/mobilenr
SITS treatment file No (TFN) (provided by database)		



## SIECV-SITS Stroke registry Case Record Form (CRF)

### I.V. Thrombolysis Stroke Patients – Standard Protocol Version

#### 2.1 Centre identification

Centre name (Hospital)		
Person who completed CRF	Name	Title
	E-mail	

#### 2.2 Patient identification *(always complete this in paper CRF, even if not used in database)*

Patient data	Age (years)	Male <input type="checkbox"/>	Female <input type="checkbox"/>
SITS treatment file No (TFN) (provided by database)			

#### 2.3 Type of acute phase intervention

<i>No specific intervention – Please use “all patients protocol form”</i>		<input type="checkbox"/>
I.v. thrombolysis		<input checked="" type="checkbox"/>
Stroke Unit care		<input type="checkbox"/>
I.a. thrombolysis		<input type="checkbox"/>
Thrombectomy		<input type="checkbox"/>
Hemicraniectomy		<input type="checkbox"/>
Carotid endarterectomy		<input type="checkbox"/>
Angioplasty/stenting, intracranial		<input type="checkbox"/>
Angioplasty/stenting, extracranial		<input type="checkbox"/>
Any other specific intervention	<input type="checkbox"/>	Which: _____

#### 2.4 Logistics

Onset-of-stroke (if unknown, best estimate)	DD-MM-YYYY*	HH:MM**(24 h)	Unknown stroke onset <input type="checkbox"/>
Arrival at hospital	DD-MM-YYYY	HH:MM (24 h)	
Start of first imaging CT/MR	DD-MM-YYYY	HH:MM (24 h)	
Start of i.v. thrombolysis	DD-MM-YYYY	HH:MM (24 h)	

#### 2.5 Modified Rankin Scale *(before onset of this stroke)*

0. No symptoms at all	<input type="checkbox"/>
1. No significant disabling symptoms	<input type="checkbox"/>
2. Slight disability but does not require substantial help from other person, can walk	<input type="checkbox"/>
3. Moderate disability, requires substantial help from other person, can walk	<input type="checkbox"/>
4. Moderately severe disability, requires substantial help from other person, unable to walk	<input type="checkbox"/>
5. Severe disability, bedbound	<input type="checkbox"/>
9. Not known	<input type="checkbox"/>

Prior disability (mRS 0-5) has other cause than stroke	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>
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#### 2.6 Currently participating in a stroke RCT

Prevention trial	<input type="checkbox"/> Which: _____	Acute stroke trial	<input type="checkbox"/> Which: _____
Other Trial	<input type="checkbox"/> Which: _____	Unknown trial	<input type="checkbox"/>
Not participating in any trial	<input type="checkbox"/>		

**3.1 Treatment**

Dose of Actilyse	Estimated weight	Measured weight	Length
Mg	Kilograms	Kilograms	Cm

  

Treatment/Explanation	At onset of this stroke			During hospital stay			At discharge		
	Yes	No	Uncertain	Yes	No	Uncertain	Yes	No	Uncertain
Aspirin < 75 mg/day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aspirin 75 mg/day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aspirin >75 mg < 200 mg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aspirin >200 mg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dipyridamole, slow release	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clopidogrel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other antiplatelet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anticoagulants, oral, with INR > 1.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heparin/heparinoids for stroke prevention/limitation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heparin/heparinoids for prophylaxis of deep venous thrombosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anti-diabetic, oral	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Insulin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diuretic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ACE inhibitor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ARB	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Betablocker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Calcium blocker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Statin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	Which:			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**3.2 Known Risk factor prior to stroke onset**

Risk factor	Explanation	Yes	No	Unknown
Hypertension	Diagnosis of hypertension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diabetes	Diagnosis of diabetes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hyperlipidemia	Diagnosis of hyperlipidemia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Current smoker	Current smoker at stroke onset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Previous smoker	Previous smoker, but stopped before stroke onset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Previous stroke earlier than 3 months	Previous diagnosis of stroke (based on clinical symptoms)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Previous stroke within 3 months	Previous diagnosis of stroke (based on clinical symptoms) within the latest 3 months	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Previous TIA/ Amaurosis fugax	Previous diagnosis of TIA or Amaurosis fugax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Atrial fibrillation	Diagnosis of atrial fibrillation (permanent or paroxysmal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Congestive heart failure	Diagnosis of congestive heart failure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**3.3 Laboratory**

Tests	Date and time		Results	
Blood glucose before treatment	DD-MM-YYYY	HH:MM (24h)	mmol/l	mg/dl
Total serum cholesterol level within 24h of onset	DD-MM-YYYY	HH:MM (24h)	mmol/l	mg/dl
Temperature	DD-MM-YYYY	HH:MM (24h)	Fahrenheit	Celsius

**3.4 Blood pressure data**

	Before treatment	2 h after treatment start	24 h after treatment start	At discharge or after 7 days
Results	Mm Hg /	Mm Hg /	Mm Hg /	Mm Hg /

## NIH – Stroke Scale (NIHSS)

Explanation	Before treatment	2h after treatment	24h after treatment	At discharge or after 7d
<b>1.a. Level of Consciousness</b> 0: Alert 1: Not alert, but arousable with minimal stimulation 2: Not alert, requires repeated stimulation to attend 3: Coma				
<b>1.b. LOC questions</b> (Ask patient the month and her/his age) 0: Answers both correctly 1: Answers one correctly 2: Both incorrect				
<b>1.c. LOC commands</b> (Ask patient to open/close eyes & form/release fist) 0: Obeys both correctly 1: Obeys one correctly 2: Both incorrect				
<b>2. Best gaze</b> (only horizontal eye movement) 0: Normal 1: Partial gaze palsy 2: Total gaze paresis or Forced deviation				
<b>3. Visual Field testing</b> 0: No visual field loss 1: Partial hemianopia 2: Complete hemianopia 3: Bilateral hemianopia (blind including cortical blindness)				
<b>4. Facial Paresis</b> (Ask patient to show teeth/ raise eyebrows & close eyes tightly) 0: Normal symmetrical movement 1: Minor paralysis (flattened nasolabial fold, asymmetry on smiling) 2: Partial paralysis (total or near total paralysis of lower face) 3: Complete paralysis of one or both sides (absence of facial movement in the upper and lower face)				
<b>5. Motor Function – Arm</b> 0: Normal (extends arms 90 <sup>o</sup> (or 45 <sup>o</sup> ) for 10 seconds without drift) 1: Drift 2: Some effort against gravity 3: No effort against gravity 4: No movement 9: Untestable (Joint fused or limb amputated) ( <i>do not add score</i> )	<b>Right</b>			
	<b>Left</b>			
<b>6. Motor Function - Leg</b> 0: Normal (hold leg in 30 <sup>o</sup> position for 5 sec without drift) 1: Drift 2: Some effort against gravity 3: No effort against gravity 4: No movement 9: Untestable (Joint fused or limb amputated) ( <i>do not add score</i> )	<b>Right</b>			
	<b>Left</b>			
<b>7. Limb Ataxia</b> 0: No ataxia 1: Present in one limb 2: Present in two limbs				
<b>8. Sensory</b> (Use pinprick to test arms, legs, trunk and face- compare side to side) 0: Normal 1: Mild to moderate decrease in sensation 2: Severe to total sensory loss				
<b>9. Best Language</b> (Ask patient to describe picture, name items, read sentences) 0: No aphasia 1: Mild to moderate aphasia 2: Severe aphasia 3: Mute				
<b>10. Dysarthria</b> (Ask patient to read several words) 0: Normal articulation 1: Mild to moderate slurring of words 2: Near unintelligible or unable to speak 9: Intubated or other physical barrier ( <i>do not add score</i> )				
<b>11. Extinction and inattention (Formerly Neglect)</b> (Use visual or sensory double stimulation) 0: Normal 1: Inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities 2: Severe hemi-inattention or hemi-inattention to more than one modality				
<b>Total Score</b>				

### 5.1 Imaging (see definitions on the last page)

CT / MR	Before treatment	After (22-36 h)	Extra
Done	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Type of imaging	CT <input type="checkbox"/> MR <input type="checkbox"/>	CT <input type="checkbox"/> MR <input type="checkbox"/>	CT <input type="checkbox"/> MR <input type="checkbox"/>
Date	DD-MM-YYYY	DD-MM-YYYY	DD-MM-YYYY
Time	HH:MM (24h)	HH:MM (24h)	HH:MM (24h)
Current infarct	Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No <input type="checkbox"/>
CT Dense artery sign	Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> Uncertain <input type="checkbox"/> No <input type="checkbox"/>
Local haemorrhage	HI 1 <input type="checkbox"/> PH 1 <input type="checkbox"/>	HI 1 <input type="checkbox"/> PH 1 <input type="checkbox"/>	HI 1 <input type="checkbox"/> PH 1 <input type="checkbox"/>
	HI 2 <input type="checkbox"/> PH 2 <input type="checkbox"/> No <input type="checkbox"/>	HI 2 <input type="checkbox"/> PH 2 <input type="checkbox"/> No <input type="checkbox"/>	HI 2 <input type="checkbox"/> PH 2 <input type="checkbox"/> No <input type="checkbox"/>
Remote haemorrhage	PHr 1 <input type="checkbox"/> PHr 2 <input type="checkbox"/> No <input type="checkbox"/>	PHr 1 <input type="checkbox"/> PHr 2 <input type="checkbox"/> No <input type="checkbox"/>	PHr 1 <input type="checkbox"/> PHr 2 <input type="checkbox"/> No <input type="checkbox"/>
Cerebral oedema (optional)	COED 1 <input type="checkbox"/> Uncertain <input type="checkbox"/>	COED 1 <input type="checkbox"/> Uncertain <input type="checkbox"/>	COED 1 <input type="checkbox"/> Uncertain <input type="checkbox"/>
	COED 2 <input type="checkbox"/> No <input type="checkbox"/>	COED 2 <input type="checkbox"/> No <input type="checkbox"/>	COED 2 <input type="checkbox"/> No <input type="checkbox"/>
	COED 3 <input type="checkbox"/>	COED 3 <input type="checkbox"/>	COED 3 <input type="checkbox"/>
ASPECTS (optional)	Score: _____ Not done <input type="checkbox"/>	Score: _____ Not done <input type="checkbox"/>	Score: _____ Not done <input type="checkbox"/>

### 5.2 Discharge or 7 days

Patient discharged before 7 days	<input type="checkbox"/>	DD-MM-YYYY	HH:MM (24 h)
7 days data	<input type="checkbox"/>		

### 5.3 Stroke diagnosis at discharge (ICD 10)

<b>Ischaemic stroke</b>	Cerebral infarct, large vessel disease with significant carotid stenosis (>50% NASCET)	I63.0 <input type="checkbox"/>
	Cerebral infarct, other large vessel disease	I63.3 <input type="checkbox"/>
	Cerebral infarct, cardiac emboli	I63.4 <input type="checkbox"/>
	Cerebral infarct, small vessel/lacunar	I63.5 <input type="checkbox"/>
	Cerebral infarct, sinus venous thrombosis	I63.6 <input type="checkbox"/>
	Cerebral infarct, other/ unusual cause	I63.8 <input type="checkbox"/>
	Cerebral infarct, multiple/ unknown cause	I63.9 <input type="checkbox"/>
<b>Involved vascular territory</b>	Anterior <input type="checkbox"/> Posterior <input type="checkbox"/> Right <input type="checkbox"/> Left <input type="checkbox"/>	
<b>Other (non-stroke) diagnosis</b>	Provide ICD 10 code if other diagnosis than stroke (normally not included in register):	:

### 5.4 Global outcome

Condition	24 h	7d/discharge
Much better	<input type="checkbox"/>	<input type="checkbox"/>
Better	<input type="checkbox"/>	<input type="checkbox"/>
Unchanged	<input type="checkbox"/>	<input type="checkbox"/>
Worse	<input type="checkbox"/>	<input type="checkbox"/>
Much worse	<input type="checkbox"/>	<input type="checkbox"/>
Dead	<input type="checkbox"/>	<input type="checkbox"/>

### 5.5 Discharge or 7 days data - Follow up at 3 months

Modified Rankin Scale	7 days/discharge	3 months
0. No symptoms at all	<input type="checkbox"/>	<input type="checkbox"/>
1. No significant disabling symptoms	<input type="checkbox"/>	<input type="checkbox"/>
2. Slight disability but does not require substantial help from other person, can walk	<input type="checkbox"/>	<input type="checkbox"/>
3. Moderate disability, requires substantial help from other person, can walk	<input type="checkbox"/>	<input type="checkbox"/>
4. Moderately severe disability, requires substantial help from other person, unable to walk	<input type="checkbox"/>	<input type="checkbox"/>
5. Severe disability, bedbound	<input type="checkbox"/>	<input type="checkbox"/>
6. Dead	<input type="checkbox"/>	<input type="checkbox"/>
7. Alive, mRS not known	<input type="checkbox"/>	<input type="checkbox"/>
9. Not known	<input type="checkbox"/>	<input type="checkbox"/>

**6.1 New events within 3 months**

1. New stroke since discharge	<input type="checkbox"/>
2. Myocardial infarct since discharge	<input type="checkbox"/>
3. Seizure since discharge	<input type="checkbox"/>
4. Other event:	Provide ICD 10:

**6.2 If dead, time and cause of death (within 3 months)**

Date of death (if not exactly known, provide best estimate)		DD-MM-YYYY	HH:MM (24h)
Primary cause of death	1. Cerebral infarct	<input type="checkbox"/>	
	2. Cerebral haemorrhage	<input type="checkbox"/>	
	3. Cerebral infarct and haemorrhage, unspecified	<input type="checkbox"/>	
	4. Myocardial infarct	<input type="checkbox"/>	
	5. Pulmonary embolism	<input type="checkbox"/>	
	6. Pneumonia	<input type="checkbox"/>	
	7. Other vascular cause	<input type="checkbox"/>	
	8. Unknown	<input type="checkbox"/>	
	9. Other cause:	Provide ICD 10:	

\* If not exactly known, provide last day patient was known free of symptoms, or best estimate

\*\* If not exactly known, provide last time patient was free of symptoms, or write nothing

# **Brain Imaging Guidelines**

- **Baseline readings**

The CT/MRI scans should be evaluated with respect to haemorrhage, any decrease in x-ray attenuation indicating a major acute ischaemic injury in the symptomatic vascular territory, or other pathology. Preferably, CT or MRI angiography imaging should be performed for identification of cerebral artery occlusion.

- **Day 1 readings**

Between 22-36 hours after start of treatment or earlier if clinically indicated

***The CT/MRI scans should be evaluated with respect to infarct size***

**Intracerebral haemorrhage, ICH – To be classified according to the following definitions:**

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- HI 1** Small petechiae along the margins of the infarct
- HI 2** A more confluent petechiae within the infarct area but without space-occupying effect
- PH 1** Blood clot(s) not exceeding 30% of the infarct area with some mild space-occupying effect
- PH 2** Blood clots exceeding 30% of the infarct area with significant space occupying effect
- PHr 1** Small or medium sized blood clots located remote from the actual infarct; a mild space occupying effect could be present
- PHr 2** Large confluent dense blood clots in an area remote from the actual infarct; significant space occupying effect may be present

**Cerebral oedema, COED – To be classified according to the following criteria:**

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- COED 1** Focal brain swelling up to one third of the hemisphere
- COED 2** Focal brain swelling greater than one third of the hemisphere
- COED 3** Brain swelling with midline shift

**If CT or MR angiography has been performed at baseline, a follow up examination is preferred at day 1**