

# A Study to Estimate How Often Post-stroke Spasticity Occurs and to Provide a Standard Guideline on the Best Way to Monitor Its Development

NCT06055725

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Status	RECRUITING
Sponsor	Ipsen
Enrollment	1,051 participants

## Key Eligibility Criteria

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### Inclusion (4)

- Participant must be aged 18 to 90 years at the time of providing informed consent
- First-ever clinical stroke, defined according to World Health Organization criteria as rapidly developing clinical signs of focal (at times global) disturbance of cerebral function lasting more than 24 hours, within the past 4 weeks;
- Confirmed paresis of the arms and/or legs which does not resolve within 1 day, according to the NIHSS score (a score of  $\geq 0$  on Question 5 or 6 of the scale) within 2 weeks after the stroke
- Capable of giving informed consent which includes compliance with the requirements and restrictions listed in the ICF and in this protocol

### Exclusion (5)

- Upper or lower extremity functional impairment prior to stroke per investigator judgement (e.g., modified Rankin Scale  $\geq 2$ );
- Presence of significant/major neurological impairment that might affect muscle tone (other than limb paresis);
- Severe multi-impairment or diminished physical condition before stroke that could have caused paresis/spasticity/motor deficit per investigator judgement;
- Life expectancy of less than 12 months as a result of severity of stroke or other illnesses (e.g. cardiac disease, malignancy, etc.)
- Participation in any interventional study

## Locations (59 total)

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Loma Linda, Anderson, California, United States  
University Of California, Los Angeles Medical Center, Los Angeles, California, United States  
University of South Florida (USF) - Morsani Center (USF Health Carol and Frank Morsani Center for Advanced Healthcare), Florida City, Florida, United States  
... and 56 more locations