

Head position and cerebral blood flow in acute ischemic stroke patients: Protocol for the pilot phase, cluster randomized, Head Position in Acute Ischemic Stroke Trial (HeadPoST pilot).

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Abstract

RATIONALE: Few proven interventions exist for acute ischemic stroke (AIS), and most are expensive and restricted in applicability. Lying flat 'head down' positioning of AIS patients has been shown to increase by as much as 20%, mean cerebral blood flow velocities (CBFV) measured by transcranial Doppler (TCD) but whether this translates into clinical improvement is uncertain.

AIM: To determine if the lying flat position increases mean CBFV in the affected territory as compared to the sitting up position in AIS patients.

METHODS AND DESIGN: Head Position in Acute Ischemic Stroke Trial (HeadPoST pilot) is a cluster randomized (clusters being months), assessor-blinded end-point, phase IIb trial, where consecutive adults with anterior circulation AIS within 12 h of symptom onset are positioned to a randomized position for 48 h with TCD performed serially.

STUDY OUTCOMES: Primary outcome is mean CBFV on TCD at 1 and 24 h after positioning. Secondary outcomes include: serious adverse events, neurological impairment at seven days, and death and disability at 90 days.

SAMPLE SIZE ESTIMATES: Assuming an increase of 8.3 (SD 11.4) cm/s in average of mean CBFV when tilted from 30° to 0°, 46 clusters are required (92 patients in total) to detect a 20% increase of mean CBFV with 90% power and 5% level of significance.

CONCLUSION: HeadPoST pilot is a cluster randomized multicenter clinical trial investigating the effect of head positioning on mean CBFV in anterior circulation AIS.

TRIAL REGISTRATION: ClinicalTrials.gov [NCT01706094](https://clinicaltrials.gov/ct2/show/study/NCT01706094).