EUROPEAN STROKE JOURNAL

B-STARS2: Early contralesional continuous theta burst stimulation (cTBS) to promote upper limb recovery after stroke: rationale and design of a phase-3 multicentre, randomised, sham-controlled, clinical trial

We aim to assess the therapeutic and cost-effectiveness of ten daily sessions of cTBS of the contralesional M1 in promoting upper limb recovery after stroke.

Participants

B-STARS2

A phase-3 multicentre, double-blind, randomized sham-controlled clinical trial

Patients with ischaemic stroke or intracerebral haemorrhage with upper limb paresis

Intervention

Randomized 1:1

Active cTBS
227 patients

Sham cTBS
227 patients

Intervention
- 10 daily sessions of active or sham cTBS of the contralesional M1
- Combined with regular care upper limb therapy
- Started within 3 weeks after stroke

Outcomes

Primary:
Fugl-Meyer Upper Extremity assessment at 90 days after stroke

Secondary:
Upper limb recovery
Participation
Cost-effectiveness
Quality of life

Follow-up:
90 days, 12 months after stroke

Vink, J. J. T., et al. European Stroke Journal, 2025 j.j.vink-5@umcutrecht.nl doi.org/ 10.1177_23969873251355937