

PRINCESS2 SUBSTUDY

Long-Term Functional, Cognitive, and Psychological Outcomes After Cardiac Arrest: Extended Follow-Up from the PRINCESS 2 trial

Study objective

This substudy aims to evaluate the effect of early transnasal cooling, compared with normothermia, on psychological, cognitive, and functional outcomes in patients surviving cardiac arrest.

Hypothesis

Early transnasal evaporative cooling initiated at the scene of arrest improves mental health, cognition and function at 90 days and 12 months after out-of-hospital cardiac arrest (OHCA) compared to normothermia.

Study Design/Methods

This study will include patients with OHCA with initial shockable rhythm, enrolled in the PRINCESS2 trial. Patients will be treated according to the group allocation in the main trial: intra-arrest hypothermia followed by systemic hypothermia to 33 °C for 24 hours (intervention) or standard of care with fever control for 72 hours (normothermia). A structured follow-up will be conducted at 90 days and 12 months after cardiac arrest. At the 90-day visit, participants will be screened for mild cognitive impairment using the Montreal Cognitive Assessment (MoCA) or the T-MoCA if the follow-up is conducted by telephone. Before the visit, participants will receive questionnaires to complete regarding psychological and functional sequelae (The Patient Health Questionnaire 9, Generalized Anxiety Disorder 7 Item Scale, PTSD Checklist for DSM-V, subjectively evaluated cognition, 1 question, Two Simple Questions about recovery, Modified Fatigue Impact Scale and World Health Organization Disability Assessment Schedule, 12 questions). At 12-months, the patients will fill out the same questionnaires plus a questionnaire about work ability (Work Ability Index).

Contact

PRINCESS2 trial team: trial@princess2.org