CO₂ STUDY

Trial schema

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│ 704 patients aged ≥ 50 years, undergoing planned heart valve       │
│ repair or replacement surgery via partial or full sternotomy or    │
│ thoracotomy using central or peripheral perfusion cannulae         │
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704 patients aged ≥ 50 years, undergoing planned heart valve repair or replacement surgery via partial or full sternotomy or thoracotomy using central or peripheral perfusion cannulae

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Consent obtained

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Pre-operative assessments: NIHSS, confusion assessment method (CAM), functional status, neurocognitive function, quality of life (SF-12)

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Eligibility confirmed

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Randomised (1:1)
Ideally 30 minutes prior to operation

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IMP group	**Placebo group**
CO2 insufflation (5.0L/min)	Medical air insufflation (5.0L/min)
Initiated before cannulation for CPB	Initiated before cannulation for CPB
until 10 minutes post CPB	until 10 minutes post CPB

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Mechanistic sub-study (100 patients - Bristol centre only)
Microembolic load measured by transcranial doppler ultrasound

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Post-surgery assessments
- Day 3: NIHSS and CAM
- Between 2-10 days: DWMRI (ideally between 2-7 days and no more than 10)
- 3 months: NIHSS, CAM, functional status, neurocognitive function and quality of life (SF-12), survival

SAE collection from randomisation to 3 month follow up