RECAST-3

SITE INVESTIGATOR MEETING

Remote Ischaemic Conditioning After Stroke 3 (RECAST-3)

A multicentre randomised controlled trial

12/09/2024

recast-3@nottingham.ac.uk

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REMOTE ISCHAEMIC CONDITIONING AFTER STROKE TRIAL 3

AGENDA

1. Trial PICO
2. Sites and recruitment update
3. Trial updates
4. Questions

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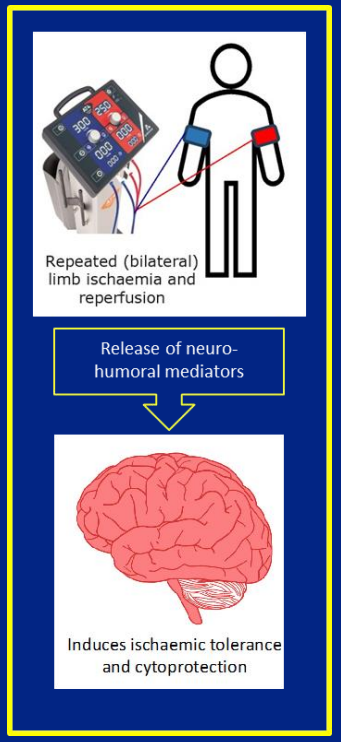
TRIAL PICO

- **Setting:** 60 UK NHS Trusts
- **Population:** 1,300 patients with acute (≤24 hours) ischaemic stroke
- **Intervention:** 4 cycles of intermittent bilateral limb ischaemia - alternating 5 minutes inflation (+20 mmHg above systolic BP) followed by 5 minutes deflation of bilateral upper arm blood pressure cuffs. Twice daily (am/pm) for 14 days/28 doses
- **Control:** Bilateral upper arm blood pressure cuffs inflated to 50 mmHg for 4 cycles. Twice daily (am/pm) for 14 days/28 doses
- **Primary Outcome:** Death or dependency at day 90 (mRS ordinal shift analysis)



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SITES & RECRUITMENT UPDATE

Sites open (n=14)
Participants (n=15)

Recruitment target: 1-2 per site per month

Open sites (14):

Site	Participants
Royal Derby Hospital	7
Queen's Medical Centre, Nottingham	2
Fairfield General Hospital, Bury	0
Aberdeen Royal Infirmary	1
UCLH	3
Morriston Hospital, Swansea	1
Bronglais General Hospital, Aberystwyth	0
Bradford Royal Infirmary	0
Southampton General Hospital	0
James Cook University Hospital, Middlesbrough	0
Salford Royal Hospital	0
Leighton Hospital, Crewe	1
Charing Cross, London	0
Leicester Royal Infirmary	0

Sites in set up having received the LIP (7):

St. George's Hospital, London
King's College Hospital, London
Princess Royal University Hospital, London
Royal Hallamshire Hospital, Sheffield
Royal Stoke University Hospital
Sunderland Royal Hospital
Southend University Hospital

Please continue to send monthly screening logs to RECAST-3@nottingham.ac.uk

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SITES & RECRUITMENT UPDATE

Thank you to everyone that has sent screening logs so far.

Key reasons for patients being excluded reported by sites to date:

Exclusion reason	%
NIHSS 4 or lower	26.5
>24 hours	25.3
ICH	8.6
NIHSS out of 5-25 range (unspecified)	8.1
Expected repatriation	6.1
Presented <24 hours OOH	3.9
Non stroke/diagnosis not confirmed within 24 hours	3.4
mRS >3	3.3
Dementia	2.0
Significant co-morbidity (life expectancy <6 months)	1.6
No onset time	1.3
Palliative	1.2
NIHSS 26 or higher	0.9
Too unwell	0.8
Can't give 4 doses before weekend and no capacity for weekend hours	0.8
No doctors on del log	0.8
Malignancy	0.8
Seizure	0.8
Declined	0.7
CT normal	0.7
CT normal, not treated as stroke	0.6
Taking part in another trial (no co-enrolment agreed)	0.5

Exclusion reason	%
Haemorrhagic transformation of infarction PH2	0.3
Gone for MT then >24 hrs	0.3
SBP <80 mmHg	0.2
Coma GCS <8	0.2
Paused to recruitment, no capacity	0.2
Known pregnancy	0.1
Sectioned due to mental health	0.1
BM <3.0mmol/L	0.0
Significant tissue injury of the upper limbs	0.0

Data suggests that by changing the NIHSS range to 4-25 (currently 5-25) and increasing the inclusion window from <24 hours to <48 hours post stroke onset will improve recruitment.

- Do sites agree?
- Any other barriers not reported?

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TRIAL UPDATES

Amendments: SA0724

- Eligibility can be confirmed and consent taken by members of the research team who have local approval to do so and are authorised on the delegation log with the consent taking role:
  - Medics
  - Research nurses
  - Research practitioners
  - Research Coordinators
  - Research associates

Implementation date 16/09/2024

- An 'Eligibility Checklist' is available
- Queries should be discussed with the medical team
- Please document eligibility confirmation in medical notes

To update the delegation log to include the consent taking role, please ask your PI to (1) log into the RECAST-3 database, (2) mark your delegation log status as 'role finished', (3) re-authorise you onto the delegation log having selected code 'J'.

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TRIAL UPDATES

Amendments: SA0724

- SA0724 Updated documents (please send us a copy of your localised versions):
  - Protocol v5.0 20240507
  - England Consultee Information Sheet Final v3.1 20240507
    (NB:- footer correction via MA0624)
  - England PIS Re-consent Final V3.1 20240507
  - England PIS V3.1 20240507

Scottish information sheets updated separately via MA0524 (all now v4.1, 20240507)

Upcoming amendments

- Plan to increase reporting timeframe for all SAEs/SADEs to 28 days (currently 20 days). Fatal SAEs and safety outcomes will continue to be reported until day 90.

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TRIAL UPDATES

Database updates:

- Treatment log CRF updated to enable entry of right arm only BP/HR values where necessary.
- To accommodate missed delivery of the intervention over weekends and bank holidays, treatment logs can be submitted up to Day 23.

Recent queries:

Cuff orientation	Acceptable to position with tubing hanging down or exiting upwards.
Overseas patients	Can be recruited if Day 90 follow up can be completed with ppt or NOK. Please obtain permission to contact directly without an alive and well check and provide a GP letter to pass on to their GP.
Participants initially treated as stroke but later deemed not a stroke	Investigator's discretion as to whether the intervention should continue.
Bruising or skin redness	Report using SAE CRF if interferes with treatment regimen. Redness on the arms not deemed clinically significant does not need to be reported and the intervention can continue.

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End slide

Questions?

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