Paramedic Initiated Lisinopril For Acute Stroke

[] Prospectively registered Submission date Recruitment status 23/09/2010 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 10/01/2011 Completed [X] Results [] Individual participant data **Last Edited** Condition category 04/10/2013 Circulatory System

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Gary Ford

Contact details

Institute for Ageing and Health The Medical School Newcastle University Newcastle upon Tyne United Kingdom NE2 4HH

Additional identifiers

ClinicalTrials.gov (NCT)

NCT01066572

Protocol serial number

NCTU5248

Study information

Scientific Title

Paramedic Initiated Lisinopril For Acute Stroke: a pilot, double blinded, randomised, placebo controlled trial

Acronym

PIL-FAST

Study objectives

This study aims to assess the feasibility of a double blind parallel group randomised controlled trial of paramedic initiated treatment for patients with symptoms of recent stroke.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle and North Tyneside 2 Research Ethics Committee approved on the 19th August 2010 (ref: 10/H0907/33)

Study design

Double blind parallel group pilot randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stroke with high blood pressure

Interventions

5 - 10 mg Lisinopril or matched placebo, once per day for seven days.

The total duration of follow up will be 7 days.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Number of participants enrolled in the study per month

Key secondary outcome(s))

- 1. The proportion of suspected acute stroke patients admitted to research sites during the trial duration who fulfilled the study eligibility criteria
- 2. The proportion of study eligibile patients attended by a research-trained paramedic
- 3. The proportion of study eligible patients enrolled into the study by a research-trained paramedic
- 4. The proportion of study eligible patients approached about the research study but not enrolled, and the reasons for non-enrolment where possible
- 5. The proportion of study eligible patients not approached about the research study, and the reasons for non-approach where possible
- 6. The additional time spent on scene by research-trained paramedics to enrol a participant into

the study

- 7. Paramedic compliance with study data collection
- 8. Hospital staff compliance with study medication adminstration and data collection
- 9. The proportion of study participants with confirmed stroke who complete seven days of study medication
- 10. Clinical outcome measures are blood pressure, neurological score, dependency score and renal function
- 11. Adverse Events in control and intervention groups during the study

Outcomes will be assessed at baseline, 3 and 7 days.

Completion date

28/10/2011

Eligibility

Key inclusion criteria

- 1. Adults greater than or equal to 40 years old
- 2. New unilateral arm weakness thought to be due to acute stroke within 3 hours of symptom onset
- 3. Hypertension as defined by systolic blood pressure (SBP) greater than 160 mmHg on two consecutive seated or lying readings taken 5 10 minutes apart
- 4. Conscious (eyes open spontaneously i.e. 'A' on Alert, Voice, Pain, Unresponsive [AVPU] scale)
- 5. Patient being transported to a PIL-FAST trial site (i.e. Royal Victoria Infirmary, North Tyneside General Hospital and Wansbeck General Hospital)
- 6. Verbal consent obtained from participant or next of kin

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

Key exclusion criteria

- 1. Aged less than 40 years
- 2. Females who are pregnant, lactating or at risk of pregnancy (i.e. who are not surgically sterile or at least 1 year post last menstrual period). Females less than 56 years of age consented by a relative will be excluded as menstrual history may be unknown.
- 3. Any presentation of suspected stroke without unilateral arm weakness
- 4. Cannot establish that stroke onset time (i.e. when patient was last seen well without s symptoms) was within the last 3 hours
- 5. SBP less than 160 mmHa
- 6. Reduced level of consciousness (below 'A' on AVPU scale)
- 7. Patient not being transported to PIL-FAST trial site
- 8. Absence of participant or next of kin consent

- 9. Known to be taking ACE-inhibitor or Angiotensin II Receptor Blocker medication already
- 10. Known sensitivity to lisinopril or other ACE-inhibitor medication
- 11. Pulse greater than 120 beats per minute
- 12. Seizure activity in this illness episode (witnessed or history)
- 13. Hypoglycaemia (blood glucose less than 3.5 mmol/l)
- 14. Cannot walk independently prior to stroke (walking stick/frame is allowed)
- 15. Obvious understanding or memory problems when next of kin is absent
- 16. Significant head trauma or brain surgery in the last 3 months
- 17. Known renal failure
- 18. Known liver failure (or currently jaundiced)
- 19. Uncontrolled heart failure (breathlessness at rest)
- 20. Receiving palliative care for known malignancy
- 21. Currently enrolled in a clinical trial assessing a study drug

Date of first enrolment

29/10/2010

Date of final enrolment

28/10/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Institute for Ageing and Health

Newcastle upon Tyne United Kingdom NE2 4HH

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

ROR

https://ror.org/05p40t847

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Programme Grants for Applied Research (ref: RP-PG-0606-1241)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 01/12/2014 | | Yes | No |
| <u>Protocol article</u> | protocol | 15/06/2011 | | Yes | No |
| HRA research summary | Participant information sheet | | 28/06/2023 | No | No |
| Participant information sheet | | 11/11/2025 | 11/11/2025 | No | Yes |