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Paramedic Initiated Lisinopril For Acute Stroke

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01066572

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Gillian Watson [gillian.watson@ncl.ac.uk] to request a patient information sheet

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 measure
Number of participants enrolled in the study per month

Secondary outcome measures
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.

Overall study start date
29/10/2010

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

Age group
Adult

Sex
Both

Target number of participants
60

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 mmHg
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
England

United Kingdom

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)

Sponsor details
Joint Research Office
Level 6 Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	15/06/2011		Yes	No
Results article	results	01/12/2014		Yes	No
HRA research summary			28/06/2023	No	No