

Paramedic Initiated Lisinopril For Acute Stroke

Submission date 23/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/01/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/10/2013	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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

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 eligible 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 administration 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 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