

Implementation of pre-hospital emergency pathway for stroke - a cluster randomised trial

Submission date 03/11/2004	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/12/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/11/2022	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
Dr Assunta De Luca

Contact details
Agency for Public health, Lazio Region
Via di Santa Costanza, 53
Rome
Italy
00198
+39 (0)6 83060446
deluca@asplazio.it

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

Implementation of pre-hospital emergency pathway for stroke - a cluster randomised trial

Acronym

IMPLICA

Study objectives

Adoption of emergency clinical pathway improves early diagnosis and referral in suspected stroke patients

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Suspected stroke in pre-hospital and emergency

Interventions

The professionals working in the Emergency Medical Services will be randomised to receive training on the evidence-based critical pathway for stroke or to current practice

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Added as of 14/03/2008:

Proportion of patients with a positive CT for ischaemic stroke and symptoms onset ≤ 6 hour admitted to the stroke unit

Secondary outcome measures

Added as of 14/03/2008:

1. Proportion of patients with a positive CT for hemorrhagic stroke and symptoms onset ≤ 6 hour admitted to a neurosurgical ward
2. Proportion of patients with a positive CT for hemorrhagic or ischaemic stroke or symptoms onset >6 hour admitted to the nearest hospital
3. Proportion of ICD9CM code for stroke in emergency setting confirmed in the hospital discharge data
4. Proportion of patients with stroke confirmed by CT results
5. Proportion of patients with ischaemic stroke receiving treatment within 6 hour of symptoms onset

Overall study start date

01/02/2005

Completion date

31/08/2005

Eligibility

Key inclusion criteria

Participants included are all the professionals working in the Emergency Medical Services dealing with patients with suspected stroke

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

About 152 physicians, 280 nurses, 50 drivers will be trained on the contents of the clinical pathway. We estimated that around 750 patients will be met by the services in the 6 months of observation.

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/02/2005

Date of final enrolment

31/08/2005

Locations

Countries of recruitment

Italy

Study participating centre

Agency for Public health, Lazio Region

Rome

Italy

00198

Sponsor information

Organisation

Agency for Public Health, Lazio Region (Agenzia di Sanità Pubblica della Regione Lazio)(Italy)

Sponsor details

Via di Santa Costanza, 53

Rome

Italy

00198

+39 (0)6 83060 493

deluca@asplazio.it

Sponsor type

Government

Funder(s)

Funder type

Not defined

Funder Name

Agency for Public Health, Lazio Region

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	Study protocol	11/10/2005		Yes	No
Results article		21/01/2009	01/11/2022	Yes	No