ISRCTN13328713 https://doi.org/10.1186/ISRCTN13328713

Prediction in patients who had a stroke and needed care at an intensive care unit concerning their changes of survival and the capacity to function in daily life after their illness

Submission date
12/02/2017

Recruitment status
No longer recruiting

Registration date
18/03/2017

Overall study status
Completed

Last Edited
23/01/2019

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A stroke is a serious medical condition that occurs when the blood supply to part of the brain is cut off. Stroke is a major healthcare issue worldwide. Mortality (death rate) from stroke has declined over time, but stroke is still responsible for one of every twenty deaths in the United States. Patients with severe stroke may need treatment in an intensive care unit (ICU). The long-term consequences of stroke have been investigated thoroughly, but much less is known about those patients who need to be admitted to the ICU. The aim of this study is to find the clinical parameters, measured when these stroke patients are admitted to an ICU, that can predict the patient's long-term survival as well as their capacity to function in daily life after their illness.

Who can participate?
Stroke patients aged 18 or older, admitted via the Emergency Department (ED) to either the general or neurosurgical ICU of one of the University College London Hospitals (UCLH) in North Central London between February 2010 and May 2012

What does the study involve?
Participants are monitored for 4-6 years to see if they are still alive and if not, when they died. The participant's capacity to function in daily life is also recorded. These values are measured at two moments: when the patient leaves the hospital and after one year at their follow-up check appointment. These data are used to find out which clinical parameters predict whether patients are likely to survive a stroke, their ability to function in daily life one year after their illness, and how they progress in this ability during the first year.

What are the possible benefits and risks of participating?
There are no direct benefits and risks to participants because this study only uses patient data obtained from databases. Future stroke patients could benefit from this study, because the

results may help identify critical stroke patients who are at increased risk of death or poor functional outcome.

Where is the study run from?
University College London Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2010 to February 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Miss Mariel van Valburg (scientific)
2. Dr Bart Geerts (scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Retrospective UCLH Stroke Intensive care audit

Study information

Scientific Title
Clinical predictors of short-term and long-term survival and functional outcome of ICU-admitted stroke patients

Study objectives
This long-term follow-up study is conducted to determine the predictive value of common-used clinical parameters upon ICU admission for long-term all-cause mortality and functional outcome of adult ischaemic and intracerebral haemorrhagic stroke patients admitted to the ICU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Demographic and clinical data were obtained as part of an audit of standard care. All data were only acquired from the national, trust and hospital databases. Therefore all authors can confirm that ethics approval was not needed for this study.

Study design
Single-centre retrospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Stroke; ischaemic and intracerebral haemorrhagic cerebrovascular accident (CVA)

Interventions

Demographic and clinical data were obtained from the national, trust and hospital databases. Patients were selected if they were admitted to one of our four ICUs between February 2010 and May 2012 with a clinical diagnosis of acute ischaemic or intracerebral haemorrhagic stroke. Surviving patients were censored on February 20, 2016.

Prognostic factors for long-term all-cause post-stroke mortality will be determined by univariable and multivariable Cox proportional hazards regression analysis with log minus log plots to confirm proportionality of hazards assumption over time. Prognostic factors for good functional outcome and improved functional status will be determined with binary logistic regression.

Model development will be performed on a multiple imputed dataset with variable exclusion in a backward stepwise selection procedure set to the lowest p value in the model.

Intervention Type
Other

Primary outcome measure
All-cause mortality after ischaemic or intracerebral haemorrhagic stroke. The follow-up timepoints lie between 4 and 6 years (depending on when the patient suffered a critical stroke) or on the moment the patient died.

Secondary outcome measures
Functional outcome, measured using the modified Rankin scale at hospital discharge and at one year follow-up check appointment and recorded by the patient's primary treating physician. The original data using this ordinal scale will be dichotomised for analysis. Good functional outcome is defined as independent functional status (mRS 0-2) versus poor functional outcome, defined as dependent functional status or dead (mRS 3-6). Furthermore, transition in mRS will be taken into account, defined as improved functional status (mRS even or increased between discharge and after one year) versus declined functional status (mRS decreased between discharge and after one year).

Overall study start date
01/02/2010

Completion date
20/02/2016

Eligibility

Key inclusion criteria
1. Adult patients (aged 18 years or older) admitted via the Emergency Department (ED) to either the general or neurosurgical ICU of one of the University College London Hospitals (UCLH) in North Central London between February 2010 and May 2012
2. Clinical diagnosis of acute ischaemic or intracerebral haemorrhagic stroke, confirmed by non-contrast cranial CT scan

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Patients with a subarachnoid or subdural bleeding
2. Patients with a known intra-cerebral or intracerebellar tumour
3. Patients who suffered an in-hospital stroke
4. Patients who were referred from another ICU for the same diagnosis

Date of first enrolment
01/02/2010

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospitals NHS Foundation Trust
235 Euston Road
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London Hospital NHS Foundation Trust

Sponsor details
235 Euston Road
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England
United Kingdom
NW1 2BU

Sponsor type
Hospital/treatment centre

Website
https://www.uclh.nhs.uk/Pages/Home.aspx

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University College London Hospital NHS Foundation Trust

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal aiming within the first half year of 2017.

Intention to publish date
01/05/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Miss Mariel van Valburg.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018	23/01/2019	Yes	No