

Stroke despite treatment with blood thinners: causes and outcomes

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| Submission date 06/06/2021 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 23/07/2021 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 11/04/2022 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Atrial fibrillation is a heart condition that causes an irregular and often abnormally fast heart rate.

Anticoagulants are medicines that help prevent blood clots. They're given to people at a high risk of getting clots, to reduce their chances of developing serious conditions such as strokes and heart attacks.

Although oral anticoagulants reduce the risk of ischemic stroke in patients with atrial fibrillation (AF), they do not eliminate it. In fact, anticoagulated AF patients still have a substantial stroke risk of about 1.5% per year. There is only limited knowledge about the causes of stroke despite anticoagulation and the subsequent treatment strategies that are needed to prevent another future stroke.

Who can participate?

This is a retrospective observational study including data of adult patients (no upper age limit, both sexes) with (a) an imaging-proven ischemic stroke, (b) nonvalvular atrial fibrillation known before stroke onset and (c) treatment with oral anticoagulants at stroke onset.

What does the study involve?

This observational study will determine the most probable cause of stroke according to one of the following categories: (a) competing stroke etiology other than atrial fibrillation; (b) medication error or (c) treatment failure (neither (a) nor (b)). The study will examine the characteristics of patients stratified to these categories, as well as the subsequent prevention strategies (including but not limited to switching the type of anticoagulant and adding antiplatelets) and 3-month clinical outcomes using standard statistical methodology including multivariable regression analyses.

Where is the study run from?

The study is led by investigators from the University Hospitals of Bern, Basel and Heidelberg.

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

The study was conceived in June 2020 and data collection was completed in March 2021.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Additional identifiers

Protocol serial number

Study information

Scientific Title

Ischemic stroke despite anticoagulant therapy in patients with atrial fibrillation - causes, subsequent treatment strategies and outcomes

Study objectives

1. The causes of ischemic stroke despite anticoagulation are heterogeneous.
2. Switching the type of anticoagulant or adding antiplatelets as subsequent prevention strategies do not reduce the risk of stroke recurrence.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/09/2019, KEK Bern (Murtenstrasse 31, 3010 Bern, Switzerland; +41 31 633 70 70; info.kek.kapa@gef.be.ch), ref: 2019-01010

Study design

Multicenter observational retrospective analysis of individual patient data

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Ischemic stroke despite oral anticoagulation in patients with atrial fibrillation

Interventions

This retrospective observational study will determine the most probable cause of stroke according to one of the following categories:

(a) competing stroke etiology other than atrial fibrillation; (b) medication error or (c) treatment failure (neither (a) nor (b)).

The study will examine the characteristics of patients stratified to these categories, as well as the subsequent prevention strategies (including but not limited to switching the type of anticoagulant and adding antiplatelets) and 3-month clinical outcomes using standard statistical methodology including multivariable regression analyses.

Intervention Type

Other

Primary outcome(s)

Measured using patient records:

1. Recurrent ischemic stroke at 3 months
2. Intracranial hemorrhage at 3 months
3. All-cause death at 3 months

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

01/03/2021

Eligibility

Key inclusion criteria

Patients presenting with imaging proven ischemic stroke who had nonvalvular atrial fibrillation known before stroke onset and were on oral anticoagulant treatment at stroke onset

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

2946

Key exclusion criteria

Patients with mechanical heart valves and those without information on anticoagulant treatment at stroke onset

Date of first enrolment

01/01/2012

Date of final enrolment

31/12/2020

Locations

Countries of recruitment

Germany

Switzerland

United States of America

Study participating centre
University Hospital Bern
Freiburgstrasse
Bern
Switzerland
3010

Study participating centre
University Hospital Basel
Petersgraben 4
Basel
Switzerland
4031

Study participating centre
University Hospital Charité Berlin
Lindenberger Weg 80
Berlin
Germany
13125

Study participating centre
EOC Neurocenter Lugano
Lugano
Switzerland
6900

Study participating centre
University Hospital Heidelberg
Heidelberg
Germany
69120

Study participating centre

University Hospital Erlangen
Erlangen
Germany
91054

Study participating centre
George Washington University Hospital
Washington, DC
United States of America
20052

Study participating centre
University Hospital Mainz
Mainz
Germany
55131

Study participating centre
University Hospital Zurich
Zurich
Switzerland
8006

Study participating centre
University Hospital Lausanne
Lausanne
Switzerland
1011

Study participating centre
Warren Alpert Medical School of Brown University
Providence
United States of America
RI 02903

Sponsor information

Organisation

University Hospital of Bern

ROR

<https://ror.org/01q9sj412>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (Alexandros.Polymeris@usb.ch)

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 08/04/2022 | 11/04/2022 | Yes | No |