

# Stroke despite treatment with blood thinners: causes and outcomes

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<b>Registration date</b> 23/07/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/04/2022	<b>Condition category</b> 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?  
David J Seiffge, MD, David.Seiffge@insel.ch  
Jan Purruicker, MD, Jan.Purruicker@med.uni-heidelberg.de  
Alexandros A Polymeris, MD, Alexandros.Polymeris@usb.ch  
Thomas R Meinel, MD, Thomas.Meinel@insel.ch

## Contact information

### Type(s)

Public

### Contact name

Dr Alexandros Polymeris

### ORCID ID

<http://orcid.org/0000-0002-9475-2208>

### Contact details

Department of Neurology and Stroke Center, University Hospital Basel  
Petersgraben 4  
Basel  
Switzerland  
4031  
+41 61 328 73 19  
[alexandros.polymeris@usb.ch](mailto:alexandros.polymeris@usb.ch)

### Type(s)

Scientific

### Contact name

Dr David Seiffge

### ORCID ID

<http://orcid.org/0000-0003-3890-3849>

### Contact details

Department of Neurology and Stroke Center, Inselspital, University Hospital Bern  
Freiburgstrasse 18  
Bern  
Switzerland  
3010  
+41 31 632 21 11  
[david.seiffge@insel.ch](mailto:david.seiffge@insel.ch)

## Additional identifiers

EudraCT/CTIS number

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

KEK Bern 2019-01010

## 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

### Secondary study design

Cohort study

### Study setting(s)

Hospital

### Study type(s)

Prevention

### Participant information sheet

Not applicable (retrospective study)

### 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 measure**

Measured using patient records:

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

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

01/06/2020

### **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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

2,000 - 3,000

### **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

**Sponsor details**  
Freiburgstrasse 18  
3010 Bern  
Switzerland  
Bern  
Switzerland  
3010  
+41 31 632 21 11  
david.seiffge@insel.ch

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.insel.ch/en/>

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

## **Funder(s)**

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

## Intention to publish date

01/03/2022

## 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?
<a href="#">Results article</a>		08/04/2022	11/04/2022	Yes	No