Trial Description

Title

Structured outpatient follow-up after stroke

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In Germany, approximately 260,000 people suffer a stroke each year, a figure that will increase over the next few decades due to demographic trends. Stroke is the second most common cause of death worldwide and the third most common cause of obstruction of life years.
With an almost comprehensive range of stroke units and a dense network of rehabilitation clinics, acute care and rehabilitation treatment of stroke in Germany are at a high level. For longer-term assurance of successful treatment, however, there is a lack of structured and quality-assured further care after discharge from acute inpatient or rehabilitation treatment. It has also been shown in several studies that the proportion of patients with risk factors set according to the guidelines after release from acute inpatient treatment is still unsatisfactory. Structured cross-sector follow-up programs are a potential strategy to tap the full potential of secondary prevention as recommended in current guidelines and to prevent recurrent strokes and other complications. With the help of SANO, the effectiveness of such a follow-up program will be investigated.

Brief Summary in Scientific Language

The primary question is whether a structured cross-sectoral follow-up program (SNP) can significantly reduce the combined endpoint of recurrent stroke, myocardial infarction or death within one year of stroke compared to standard treatment.
In addition, valid data to guide the setting of risk factors and the rate of hospital admissions and other complications.

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

see SANO data sharing plan in the uploaded PDF document

Organizational Data

- DRKS-ID: **DRKS00015322**
- Date of Registration in DRKS: **2018/08/27**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2018-131184 , Ethik-Kommission bei der Landesärztekammer Rheinland-Pfalz**

Secondary IDs

Health condition or Problem studied

- ICD10: **I63.0 - Cerebral infarction due to thrombosis of precerebral arteries**
- ICD10: **I63.1 - Cerebral infarction due to embolism of precerebral arteries**
- ICD10: **I63.2 - Cerebral infarction due to unspecified occlusion or stenosis of precerebral arteries**
- ICD10: **I63.3 - Cerebral infarction due to thrombosis of cerebral arteries**
- ICD10: **I63.4 - Cerebral infarction due to embolism of cerebral arteries**
- ICD10: **I63.5 - Cerebral infarction due to unspecified occlusion or stenosis of cerebral arteries**

Interventions/Observational Groups

- Arm 1: **At the intervention centers, a cross-sectoral network will be set up before the start of the project, consisting of general practitioners, specialists, sports groups, therapists and other professional groups. After inclusion in the study, a basic examination is carried out. All patients are advised and examined in detail and concrete therapy goals are defined for all individual risk factors. Follow-up examinations take place after 1, 3, 6 and 9 months. Here, the attitude of the risk factors, the medication as well as the medical and auxiliary care of the patients are checked and, if necessary, adjusted. Follow-up visits at 3 and 6 months will be followed by structured screening for possible complications such as depression or cognitive impairment. After 12 months, a detailed final examination is carried out, in which the primary and secondary outcomes are recorded.**
- Arm 2: **Patients in the control group undergo a basic examination after inclusion in the study. Here, the patients are thoroughly examined and receive information about their disease according to the standard of the respective hospital. After 12 months, patients will be invited to a final exam, which will record the primary and secondary outcomes.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Rate of combined outcome in recurrent stroke, myocardial infarction or death within one year of stroke

Secondary Outcome

Proportion of regulatory risk factors (hypertension, diabetes mellitus, hypercholesterolemia, smoking, diet, physical activity) at one year after stroke
• Therapy adherence regarding antithrombotic medication at one year post stroke
• Rate of hospital admissions within one year of stroke
• Rate of complications (cognitive impairment, depression and anxiety, falls) or their treatment at the time of one year after stroke
• Quality of life at the time of one year after stroke
• Follow-up costs in the first year after stroke

These endpoints are measured using the following tools:
Cognitive limitations MoCA test
Depression / Anxiety PHQ-9 / GAD7
Medication Adherence Medication Adherence Rating Scale (MARS)
Quality of life EQ-5D-5L
Physical Activity IPAQ / Pedometer
Diet MONICA, nutrition questionnaire

All other secondary endpoints are determined by standardized interviews, examinations or laboratory parameters.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Neurologische Klinik, Heidelberg**
- University Medical Center **Neurologische Klinik, Mannheim**
- Medical Center **Rhön-Klinikum Campus Bad Neustadt, Bad Neustadt**
- University Medical Center **Universitätsmedizin Mainz, Mainz**
- University Medical Center **Universitätsklinikum Tübingen , Tübingen**
- University Medical Center **Universitätsklinikum Münster, Münster**
- Medical Center **medbo Bezirksklinikum Regensburg , Regensburg**
- Medical Center **Rems-Murr-Kliniken Winnenden, Winnenden**
- University Medical Center **Neurologische Klinik, Freiburg im Breisgau**
- University Medical Center **Neurologische Klinik, Mainz**
- Medical Center **Katholisches Klinikum Koblenz , Koblenz**
- Medical Center **Krankenhaus der Barmherzigen Brüder Trier , Trier**
- University Medical Center **Neurologische Klinik, Homburg**
- Medical Center **Neurologische Klinik, Klinikum Saarbrücken, Saarbrücken**
- Medical Center **Klinikum Idar-Oberstein, Idar-Oberstein**
- Medical Center **Klinikum Müchen-Bogenhausen, München**
- Medical Center **Neurologische Klinik, Bezirksklinikum Günzburg, Günzburg**
- Medical Center **Neurologische Klinik. Klinikum Dortmund, Dortmund**
- Medical Center **Neurologische Klinik, Ludwigshafen am Rhein, Ludwigshafen am Rhein**
- University Medical Center **Neurologische Klinik, Aachen**
- Medical Center **Neurologische Klinik, Leopodinakrankenhaus, Schweinfurt**
- Medical Center **Neurologische Klinik, Klinikum Tutzing, Tutzing**
- University Medical Center **Neurologische Klinik, Würzburg**
- University Medical Center **Neurologische Klinik, Erlangen**
- Medical Center **Neurologische Klinik, Klinikum Darmstadt, Darmstadt**
- Medical Center **Neurologische Klinik, Klinikum Fulda, Fulda**
- Medical Center **Neurologische Klinik, Klinikum Frankfurt Höchst, Frankfurt a.M.**
- University Medical Center **Neurologische Klinik, Essen**
- Medical Center **Neurologische Klinik, Klinikum Siegen, Siegen**
- University Medical Center **Neurologische Klinik, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/01/10**
- Target Sample Size: **2790**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Awareness about the project
No severe disability before index stroke (mRS 0-1)
Insurance in the statutory health insurance
There are at least one of the following risk factors: arterial hypertension, hypercholesterolemia, diabetes mellitus, smoking, atrial fibrillation
written consent to study participation

Exclusion criteria

Age <18 years
Relevant cognitive impairment, advanced dementia (assessed by the study physician)
mRS after stroke> 3 at the time of screening for the study
Former stroke (ischemic insult or cerebral hemorrhage, former TIAs are not an exclusion cause)
Life expectancy <3 years (due to the time of the screening of known diseases)
Alcohol, medications or drug addiction as assessed by the study doctor
Severe psychiatric illness as assessed by the study physician
Missing family doctor and no willingness to select a family doctor at short notice
No consent of the responsible family doctor to participate in the study
Nursing home or long-term care before the index stroke
Existing legal care of the patient
Inadequate knowledge of German, very severe aphasia
Lack of availability of the clinic for follow-up
No consent to attend the clinic visits after 1, 3, 6 and 9 months
Rare stroke cause for which there are no evidence-based recommendations for secondary prophylaxis (dissection, vasculitis, drug-associated strokes, strokes during pregnancy, etc.)
Participation in drug law (AMG) study
Other reasons according to the study doctor, which can not guarantee the application or implementation of the intervention

Addresses

- **Primary Sponsor**

Primary Sponsor

Klinikum Ludwigshafen am Rhein
Bremserstr. 79
67063 Ludwigshafen am Rhein
Germany

Telephone: **0621-5034200**
Fax: **0621-5034202**
E-mail: **graua at klilu.de**
URL: **https://www.klilu.de/content/index_ger.html**

■ **Contact for Scientific Queries**

Institut für Klinische Epidemiologie und Biometrie (IKE-B) der Universität Würzburg
Mr. Prof. Dr Peter Uwe Heuschmann
Josef-Schneider-Str. 2 / Haus D7
97080 Würzburg
Germany

Telephone: **+49 (0)931 / 201 47308**
Fax: **+49 (0)931 / 201 647310**
E-mail: **epidemiologie at klinik.uni-wuerzburg.de**
URL: **http://www.epidemiologie.uni-wuerzburg.de/startseite/**

■ **Contact for Public Queries**

Klinikum Ludwigshafen am Rhein
Mr. Prof. Dr. Armin Grau
Bremserstr. 79
67063 Ludwigshafen am Rhein
Germany

Telephone: **0621-5034200**
Fax: **0621-5034202**
E-mail: **graua at klilu.de**
URL: **https://www.klilu.de/content/index_ger.html**

Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Innovationsausschuss beim Gemeinsamen Bundesausschuss
Wegelystraße 8
10623 Berlin
Germany

Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)

Innovationsausschuss beim Gemeinsamen Bundesausschuss
Wegelystraße 8
10623 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **info at if.g-ba.de**
URL: **https://innovationsfonds.g-ba.de/**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Further trial documents **SANO_Data sharing plan**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*