

Study Protocol – Final Version

(31. October 2013)

Pragmatic trial of multifaceted intervention (STROKE-CARD care) to reduce cardiovascular risk and improve quality-of-life after ischaemic stroke and transient ischaemic attack

Short Title: Stroke Card

Project Team:

Principal Investigator: J. Willeit

Co-Investigators: S. Kiechl (incl. Biometry), M. Knoflach, K. Kofler, A. Tür, T. Töll, G. Schönherr, H. Gothe, S. Preindl, W. Poewe

Sponsor & Study Center:

Medical University Innsbruck

Consortium:

The *Stroke Card* consortium is composed of MUI, CEMIT, UMIT, TILAK, TGKK, TGF, and the enterprises Boehringer Ingelheim and Otto Bock. The consortium *en total* meets yearly. The enterprises were not involved in the study design, have no influence on the analysis, interpretation and publication of data, and have no influence on clinical decisions.

Scientific Project lead:

Medical University Innsbruck, Department of Neurology (Head: Prof. Poewe)

Project organization:

CEMIT

Study Design:

Prospective uni-center block-randomized open interventional trial with blinded outcome assessment

Study Duration:

36 months

SPONSOR OF THE STUDY**TRANSLATED****Obligation to confidentiality**

All data and information in this protocol are confidential and are allocated to the principal investigators, potential principal investigators, health authorities and ethical committees for inspection and review. Publication is not permitted without written consent. An exemption is subject to written informed consent by a study participant. After written informed consent, all obligations within this protocol are binding for all parties.

Statement of the sponsor

The following study protocol has undergone a critical review. The content agrees with the current risk-benefit estimation for the described methods as well as the moral, ethical and scientific principles of the latest valid version of the Declaration of Helsinki and the local legal obligations and regulations.

Prof. Dr. Johann Willeit*Principal Investigator of the Study*

Location, Date, Signature

o. Univ.-Prof. Dr. Werner Poewe*Head of Department**Representative of the Medical University of Innsbruck*

Location, Date, Signature

The above mentioned parties acknowledge, that they read this study protocol and confirm the completeness of all data and information relevant for conduct of the study. Moreover, they confirm to conduct the study according to the following protocol. It has been agreed that all unpublished information and data are obliged to confidentiality.

SIGNATURES

TRANSLATED

Study title: Pragmatic trial of multifaceted intervention (STROKE-CARD care) to reduce cardiovascular risk and improve quality-of-life after ischaemic stroke and transient ischaemic attack

Short title: Short Title: Stroke Card

Statement of the statistician:

I have read this study protocol and approve to the content. I confirm that this protocol includes all relevant information for conduct of the study. I agree to conduct the study according to the following protocol. I will follow the moral, ethical and scientific principles of the latest valid version of the Declaration of Helsinki as well as local legal obligations and regulations.

I will report all alterations, which are subject to the accountability of every party who signed this document.

I confirm treating all unpublished information and documents as strictly confidential. These documents include the study protocol, the case report forms and other scientific data.

Prof. Dr. Stefan Kiechl

Statistician

Location, Date, Signature

SIGNATURES

TRANSLATED

Study title: Pragmatic trial of multifaceted intervention (STROKE-CARD care) to reduce cardiovascular risk and improve quality-of-life after ischaemic stroke and transient ischaemic attack

Short title: Short Title: Stroke Card

Statement of the local principal investigator:

I have read this study protocol and approve to the content. I confirm that this protocol includes all relevant information for conduct of the study. I agree to conduct the study according to the following protocol. I will follow the moral, ethical and scientific principles of the latest valid version of the Declaration of Helsinki as well as local legal obligations and regulations.

I confirm treating all unpublished information and documents as strictly confidential. These documents include the study protocol, the case report forms and other scientific data.

Location, Date

Prof. Dr. Johann Willeit

Signature

Disease management:

Our disease management program complies with the respective guidelines of the AHA (Stroke 2004; 35: 1527-30), focuses on patient empowerment, patient self-management education, routine reporting to the GP, evidence-based decision making, shared knowledge, and cooperation among physicians.

Whereas disease management programs typically rely on expert opinion, our initiative will move from a purely empirical approach to a highly structured, individualized and evidence-based procedure with a professional outcome and health economy analysis. In the case of positive evaluation (improved quality without increased costs), the stroke card concept is ready for clinical implementation and can serve as a model for other disease management initiatives.

Mission statement:

Stroke is the leading cause of disability and morbidity in the Western world and will extend its lead based on the continuous aging of European populations. Apart from persistent deficits, potentially avoidable medium- and long-term complications are significant contributors to post-stroke functional impairment and an appealing target for concerted interventions. Moreover, there is a substantial gap between risk factor management in real life and that recommended by international guidelines, resulting in a large number of avoidable recurring events.

Building on the integrative stroke network in Tyrol, one of the most advanced in the field (<http://www.tirol.gv.at/themen/gesundheit/krankenanstalten/schlaganfall/projekt/>), we will initiate a comprehensive stroke management program called *Post-Stroke Disease Management – Stroke Card*.

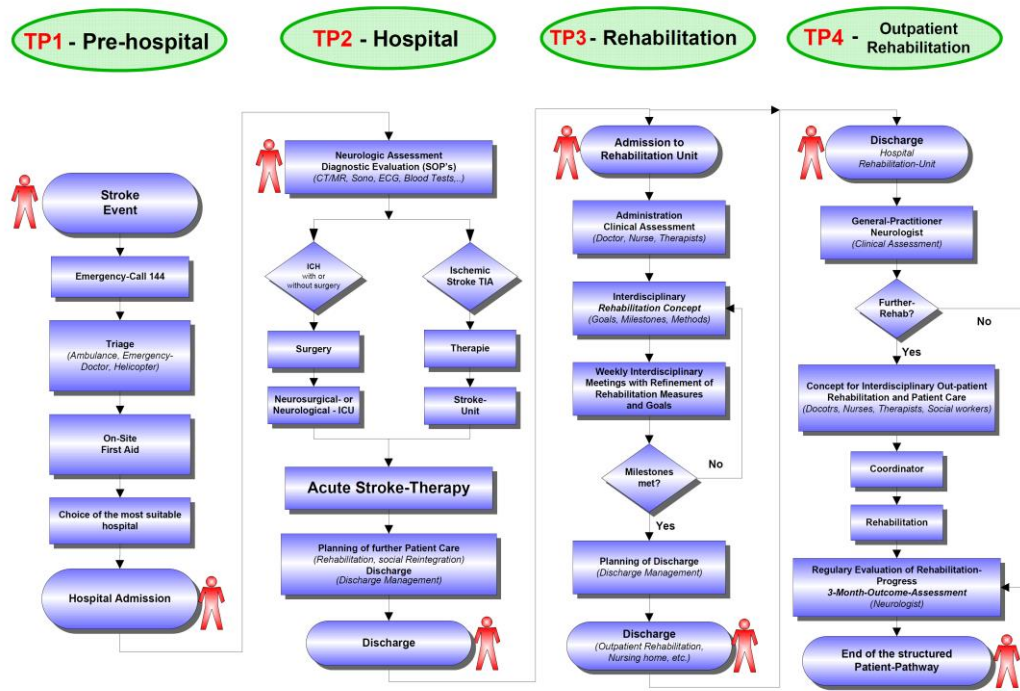


Figure: Organization of the Integrative Stroke Network in Tyrol

Generic Objectives:

- Early detection or prevention of post-stroke complications, estimation of the patient's demand for nursing services and support, guideline-conform secondary prevention with full achievement of target levels, lifestyle modifications and outcome assessment after 3 and 12 months, assessment of 12-Mo body functioning (impairment), activity (disability) and participation (handicap and QoL).
- Detailed assessment of patient adherence to drug prescriptions as well as lifestyle modifications and analysis of its key determinants.
- Implementation of a simple electronic tool („My Stroke Card“) for patients capable of storing data, displaying risk factor levels over time (graphs), giving feedback about target level achievement (red, orange, green), providing information (recommendations, self-administered patient training programmes, etc), and unraveling post-stroke complications (modified post-stroke checklist). We will make use of an existing computer-based health evaluation software (CHES), which is currently successfully applied for Web-monitoring of oncological patients and will be adopted to the particular demands of the current project (ESD - Evaluation Software Development Rumpold & Holzner OG). The “My Stroke Card” is also available in print version for patients without PC access.
- Scientific proof that this disease management program ameliorates functional outcome and patient wellbeing (QoL), and improves secondary prevention of stroke and other vascular sequels without raising costs.
- Refinement of *Stroke Card* components in the case of success to end up with a condensed practicable approach for broad routine use, and identification of subgroups with the most pronounced benefit.

Design and population enrolment:

Stroke Card is a prospective uni-center block-randomized open interventional trial with blinded outcome assessment comparing two standards of post-stroke patient care which both comply with the current state-of-the-art. It is currently unknown which standard is superior in terms of the primary and secondary outcome parameters. The results will assist in further optimizing post-stroke patient care in the Tyrol.

Consecutive patients treated at the Department of Neurology in Innsbruck with ischemic stroke or high-risk TIA will be allocated to either standard care or extended standard care according to the *Stroke Card* concept and will be enrolled during the initial hospital stay.

Allocation is done using a 2 to 1 allocation ratio and block randomization (blocks á 4-8 weeks, schedule below). This enrolment procedure will result in 1600 patients in the *Stroke Card* and 800 in the *Control* group and ensures carefully balanced baseline characteristics. Recruitment

of 800 patients per year is feasible given an annual number of suitable patients of about 1000 (in house statistics and lessons from the integrative stroke network in Tyrol). We expect that only few patients will withdraw their consent to participate, these patients will not be replaced by new patients.

Endpoints and targets:

We perform blinded outcome assessment at 12 months. All outcomes will be calculated on an intention-to-treat basis (primary analysis) and on a per-protocol basis (sensitivity analysis).

Co-Primary endpoints

- Recurrent (post-discharge) cardiovascular events (composite of myocardial infarction, stroke, and vascular death)
- Health-related QoL (European Quality of Life-5 Dimensions EQ-5D-3L – overall health utility score) – this QoL score can be converted into monetary units and thus supports the health economy priority

Secondary endpoints

- Recurrent stroke and TIA (both ischemic and hemorrhagic)
- Overall mortality at 12 months
- Functional outcome (mRS \leq 2 and shift analysis) and occupational reintegration
- QoL: 5 individual dimensions (mobility, self-care, usual activities, pain and discomfort, anxiety and depression)
- Target level achievement (see appendix)
- Health-economic evaluation: cost-utility analysis (costs assessed in monetary units) and benefit measured as a non-monetary utility-adjusted outcome (quality-adjusted life-year [QALY])
- Overall (12 Mo) number of out-of-schedule consultations of physicians and out-patient hospital services

Ethics committee: Innsbruck

Schedule:

CRF, protocols – October 2013

Ethics approval in Innsbruck – November 2013

Start – January 2014 (enrolment)

End – March 2016 (last follow-up visit)

In- and Exclusion criteria:

Inclusion

- Patients with acute ischemic stroke or high-risk TIA (ABCD₂≥3 or visible DWI lesion on MRI)
- Age ≥ 18 years
- Written informed consent

Exclusion

- Patients living outside Tyrol
- Malignant or other severe disease with life-expectancy less than the expected duration of the trial
- Drug addiction or severe alcohol abuse
- Patients with persistent severe disability at discharge (mRS=5) not suitable for rehabilitation (this group will have outcome and complication assessment by a telephone interview with the caregivers according to current standards)

Role of the general practitioner:

The general practitioner maintains his/her usual position as the primary treating physician and decision maker. He/she will be informed about all exams and relevant information by medical reports. He/she will have access to risk factor self-assessments (print forms). Regular contact to and visits with the GP are crucial to the success of the program.

Standard care:

- In-hospital training (education of patients, next of kin and caregivers on risk factor management and assessment, life style improvement and compliance) both in-person and during scheduled mini-lectures including motivational interviews and behavioral strategies
- Complimentary provision of a book / information material dealing with patient and caregiver relevant aspects of stroke care
- Advise by a dietitian (general advise and individualized recommendations in patients with diabetes and obesity)
- Standardized information materials (e.g. for OAK or NOAK therapy)
- Support for smoking cessation and weight reduction if necessary or requested for
- Detailed medical reports (doctor's letter for the general practitioner and patient) at discharge containing target levels for risk factor management
- AF detection at the Stroke Unit (1-5 day monitoring) and/or at the ward (24-hour ECG)
- 3-month telephone interview for assessment of 3-mo outcome (mRS, BI) as part of the country-wide quality program of the GÖG/BIQ (including nursing allowance, living situation, support services)

- 12-month clinical visit

Extended standard care (Stroke Card):

All above plus

- Extended training with access to educational lectures at any time (education of patients and relatives), implementation of “*My Stroke Card*” containing (a) an adopted version of the ‘post-stroke checklist’ (ascertainment of post-stroke complications), (b) self-administered internet-based tools for risk factor monitoring and reinforcement of target level achievement, and (c) information and educational materials.
- 3 Mo outpatient appointment with standardized assessment of risk factors and screening for complications, problems and residual deficits (ADL, mobility, spasticity, foot-drop, fatigue, pain, incontinence, communication, mood, cognition, life after stroke, relationship with family, seizures, fatigue, syncope, falls, etc.), estimation of the patient’s demand for nursing services and support, guideline-conform secondary prevention with full achievement of target levels, assessment of patient adherence to drug prescriptions. Study assessments are embedded in a standard clinical visit performed by an experienced stroke physician with usual communication to the GP (doctor’s letter).
- 6 Mo and 9 Mo visits on the discretion of the study team in case of medical needs, complications requiring follow-up, very bad risk factor control (compliance) or excessive demands of the patients or caregivers (we strive at a proportion < 5-10% of study subjects).

Positive experiences with structured support programs and web-based risk factor management have been gained for diabetes, CHD and hypertension – yet not with stroke patients.

The in-hospital phase does not differ between the two groups (except for training the extended standard care group for the use of “*My Stroke Card*” before discharge). There will be a continuous monitoring of benchmarks like duration of hospital stay, discharge NIHSS, and access to rehabilitation facilities to make sure that both groups do not receive differential attention.

Procedures and methods:

Baseline assessment:

- Demographic information, handedness, marital status, education

- Cardiovascular risk factors (standard risk factors, MS) and behaviors (pack-years), weight, BMI, WHR, smoking addiction score (Fagerstrom), diet (FFQ) and sports activities (Baecke Score pre-stroke)
- Previous cardiovascular diseases, VTE and co-morbidities
- Stroke characteristics: stroke etiology (TOAST, CCS), symptoms, MR/CT findings, hemisphere of lesion, onset, OTD time, therapy, DTNT
- Vascular co-morbidities (ABI, sonography of carotid arteries and the abdominal aorta, pulse-wave velocity as a measure of arterial stiffness, coronary calcium score and aortic calcium score if indicated, MR plaque characterization if indicated)
- Laboratory measures (see appendix)
- Baseline (NIHSS) and hospital discharge functional status (NIHSS, mRS, BI) plus functional quantitative test systems for the patient's individual deficits (see appendix)
- History of syncope and testing if appropriate (according to usual standards)
- In-hospital recurrent events (timing, progressive, recurrent)
- In-hospital complications
- Duration of stay in the acute hospital
- Vascular risk Score (10-year CVD FRS, Tyrol Score components)
- Medication at discharge
- AF monitoring in the Stroke Unit (1-5 day monitoring) and/or at the ward (24-hour ECG)
- Screening for and quantification of *Pain* (0–10 Numeric Pain Rating Scale), *Mood and Anxiety* (BDI, HADS), *Risk of Falls* (TUC, BBS), *Fatigue* (FSS), *Cognition* (MoCA), *Gait Impairment* (10-m Gait Test, TUC, FAC), *Incontinence*, *Health-related QoL* (European Quality of Life-5 Dimensions EQ-5D-3L, SS-QOL), *Nursing Demands* (services, support)

3 Mo Visit:

- Risk factor levels (blood pressure, etc), control of risk factor levels and update on medication, diet (FFQ) and sports activities (Baecke Score), weight, BMI, WHR
- Laboratory measures (see appendix, routine CVD prevention lab)
- Recurrent cardiovascular disease events
- Follow-up functional status (repetition of baseline scores) mRS, BI, FAI
- Falls, seizures, syncope, VTE, and bleeding events
- Vascular risk Score (10-year CVD FRS, Tyrol Score components)
- Caregiver Burden Score
- Screening for and quantification of *Foot Drop* (ICF and scoring of gait), *Spasticity* (modified Ashworth - quadriceps, hamstring, calf, arm flexors, etc), *Pain* (0–10 Numeric Pain Rating Scale), *Mood and Anxiety* (BDI, HADS), *Risk of Falls* (TUC, BBS), *Fatigue* (FSS), *Cognition* (MoCA), *Gait Impairment* (10-m Gait Test, TUC, FAC), *Incontinence*, *Social Reintegration* (K-

14), *Health-related QoL* (European Quality of Life-5 Dimensions EQ-5D-3L), *Nursing Demands* (services, support, deficits)

- BiQ/GÖG 3 month assessment (nursing allowance, living situation, support services, BI)
- Rehabilitation details

12 Mo Visit:

- Risk factor levels (blood pressure, etc), control of risk factor levels and update on medication, sports activities (Baecke Score), weight, BMI, WHR
- Laboratory measures (see appendix, routine CVD prevention lab)
- Recurrent cardiovascular disease events*
- Falls, seizures, syncope, VTE, and bleeding events*
- Follow-up functional status (repetition of baseline scores) mRS, BI, FAI plus functional quantitative test systems for the patient's individual deficits (same set as used at baseline)*
- Vascular risk Score (10-year CVD FRS, Tyrol Score components)
- Caregiver Burden Score
- Screening for and quantification of *Foot Drop* (ICF and scoring of gait), *Spasticity* (modified Ashworth - quadriceps, hamstring, calf, arm flexors), *Pain* (0–10 Numeric Pain Rating Scale), *Mood and Anxiety* (BDI, HADS), *Risk of Falls* (TUC, BBS), *Fatigue* (FSS), *Cognition* (MoCA), *Gait Impairment* (10-m Gait Test, TUC, FAC), *Incontinence*, *Social Reintegration* (K-14, relationship with family), *Health-related QoL** (European Quality of Life-5 Dimensions EQ-5D-3L)
- Follow-up of vascular status in patients with a putative atherothrombotic origin of stroke / TIA (sonography of carotid arteries and plaque characterization if appropriate, pulse-wave velocity)
- Nursing allowance, living situation, support services
- Quantity of out-patient rehabilitation efforts (units) and overall in-patient rehabilitation (days)
- Patient satisfaction with post-stroke care

* These data will be assessed by study personnel blinded to the allocation of patients in the standard and extended care group.

CRF:

The CRF will be available in October 2013. The *Stroke Card* represents a multidisciplinary standardized assessment tool for stroke patients administered 3M post stroke and includes (a) a thorough assessment of residual deficits and screening for post-stroke complications and demands (post-stroke checklist: ADL, mobility, foot-drop, spasticity, pain, incontinence, communication, mood, cognition, life after stroke, relationship with family, etc), (b) vascular

co-morbidities, (c) nursing aspects, and (d) CVD risk stratification and check of individual risk factor levels.

The trial does not include any experimental treatments but compares usual care with more intensive care based on international guidelines. According to the *Stroke Card* concept acute stroke management does not finish with hospital discharge but involves intensive patient support and empowerment thereafter with a standardized check-up at three months.

Organization:

The entire study team will meet at the beginning of the Program (Kick-off), half-way of the study and after completion.

Key references:

1. Faxon DP, Schwamm LH, Pasternak RC, Peterson ED, McNeil BJ, Bufalino V, Yancy CW, Brass LM, Baker DW, Bonow RO, Smaha LA, Jones DW, Smith SC Jr, Ellrodt G, Allen J, Schwartz SJ, Fonarow G, Duncan P, Horton K, Smith R, Stranne S, Shine K; American Heart Association's Expert Panel on Disease Management. Improving quality of care through disease management: principles and recommendations from the American Heart Association's Expert Panel on Disease Management. **Stroke** 2004; 35: 1527-30.
2. Wissel J, Olver J, Sunnerhagen KS. Navigating the Poststroke Continuum of Care. **Journal of Stroke and Cerebrovascular Diseases** 2013; 22: 1-8.
3. Donnan GA, Fisher M, Macleod M, Davis SM. Stroke. **Lancet** 2008; 371: 1612–23
4. Brainin M, Norrving B, Sunnerhagen KS, Goldstein LB, Cramer SC, Donnan GA, Duncan PW, Francisco G, Good D, Graham G, Kissela BM, Olver J, Ward A, Wissel J, Zorowitz R. Poststroke chronic disease management: towards improved identification and interventions for poststroke spasticity-related complications. **International Journal of Stroke** 2011; 6: 42-46.
5. Leistner S, Michelson G, Laumeier I, Ahmadi M, Smyth M, Nieweler G, Doehner W, Sobesky J, Fiebich JB, Marx P, Busse O, Köhler F, Poppert H, Wimmer ML, Knoll T, Mudersbach P, Audebert HJ: Intensified secondary prevention intending a reduction of recurrent events in TIA and minor stroke patients (INSPIRE-TMS): a protocol for a randomised controlled trial. **BMC Neurology** 2013; 13: 11.
6. Integrative Stroke Network in Tyrol – Final Report on <http://www.tirol.gv.at/themen/gesundheit/krankenanstalten/schlaganfall/projekt/>

Appendix A

Biobank: A unique resource of patient and proband samples will be collected among consecutive stroke patients (target number n=2400) after a signed informed consent as part of our *Disease Management Stroke* initiative. Samples will be drawn within 24 hours after admission and 3 and 12 months thereafter. In addition to plasma (10 aliquots á 500 µL and 5 x 500 µL PPP per evaluation) and serum (10 aliquots á 500 µL per evaluation), whole blood and urine samples (10 mL) will be archived in safeguarded freezers at -80°C (locked room and locked freezer). Temperature is permanently monitored by the hospital's technical service unit with backup capacity available in case of a technical defect. The newly established biobank will continue on a long-term basis. Sample storage complies with the OECD guidelines and is in accordance with the national Bioethics Commission Report (recommendations of the Austrian bioethics commission). The management board consists of the key investigators of the project involved in sample collection and will ensure protection of the rights and wellbeing of study participants, serve as a scientific board for future research activities and assign qualified personnel to the maintenance of the biobank. Privacy of the participants' data will be secured by appropriate measures (pseudonymisation) and encryption of data, central databases with secure and limited access).

On a long run, the Biobank will be used to unravel novel prognostic and etiological factors of ischemic stroke. Fund raising is required for this purpose. We plan assess inflammation markers (cytokine, MPO, MMPs, oxLDL), regulators of bone metabolism and vascular calcification (OPG, RANKL, osteocalzin, Vitamin D), measures of insulin resistance (HOMA, insulin, adiokines), and common genetic polymorphisms and markers. The list will be subjects to further refinement dependent on the continuous medical progress.

IT solution: ESD - Evaluation Software Development Rumpold & Holzner OG will design a web platform providing extensive information material on all aspects of stroke (care, prevention and management), electronic tools for risk factor control (long-term recording with a simple graphical display and print of trends and patient reinforcement), self-administrable screening questionnaires for post-stroke complications (with automatic scoring and interpretation) and a reminder for appointments within the programme (visits, to-do-list, self-evaluation). ESD will build on the existing product CHES and adopt it to the demands of the current project. Patients (and/or relatives and/or nurses) will be trained to use "My Stroke Card" on PCs or as apps on cellphones already during the initial hospital stay.

Health-economic evaluation: Health-economic (HE) evaluation of the Stroke Card concept relies on two types of datasets. (1) The data of the project database cover information on health status and status changes over time, as well as health care utilization (pharmacological and surgical interventions, remedies, medical devices) which can be expressed in monetary

units. Additionally, health-related Quality of Life (QoL) assessment will be employed. Benefit will be measured as a non-monetary but utility-adjusted outcome, the quality adjusted life year (QALY). (2) Routine claims data provided by the Tyrolean regional sickness fund (TGKK) will be made accessible to HE evaluation. Claims data are continuously collected by the sickness fund. Data processing within the sickness fund is mainly intended for billing and reimbursement purposes. For scientific use the data have to be validated, plausibilized, and adapted to the HE evaluation necessities. These efforts will be rewarded by the advantage that the data are unbiased and hence mirror the real world situation in an ideal manner, which is of paramount importance for the reliability of the HE evaluation. After completion of data assessment, data cleansing and merging of project-specific, hospital and health insurance data bases a comparative HE evaluation of the control and intervention groups will be performed by means of cost-utility analyses (CUA). The CUA method is a HE study approach in which the costs are assessed in monetary units and the benefit is measured as a non-monetary but utility-adjusted outcome (QALY). Strict adherence to data privacy protection will be assured according to national data security legislation.

Refinement and condensation of stroke card content: In a final step, the stroke card will be refined and condensed with the option of broad implementation in the whole of Tyrol. Specifically, we aim at omitting all components of the *Stroke Card* that did not contribute to target achievement in order to minimize its volume and the man-power required for its implementation. Another decided aim is the identification of sub-groups of stroke patients with pronounced health benefit from and cost effectiveness of the *Stroke Card* program.

Application-oriented processing and implementation of new findings: We plan to establish one of few disease management programs which were developed and evaluated according to high scientific standards. Primary objectives are to enhance adherence to prevention guidelines, to lower rates of post-stroke complications and to improve outcome (functional, QoL). Comprehensive assessment of the patient adherence to prevention regimes, especially drugs, and characterization of the key determinants thereof are of immediate relevance for a better patient compliance.

Publications: The study protocol will be registered at and published in ClinicalTrials.gov. We aim at publishing the main study findings in peer-reviewed medical journals.

Appendix B

Targets for risk factor management:

- Blood pressure < 140/90 (<130/85 in selected patients with diabetes, renal impairment or small-vessel disease) in > 85% of self-assessments and at follow-up
- Hba1c<7.5%
- Nicotine abstinence (Cotinin)
- LDL cholesterol < 100 mg/dL or 70 mg/dL in high-risk patients (intra- or extracranial vessel stenosis, instable plaques, atherothrombotic strokes)
- Metabolic Syndrome (NCEP-ATPIII): reduction of component number by 1
- Physical activity > 30 minutes at least 3 times per week
- Platelet inhibitor or (N)OAK
- Oral anticoagulation (INR 2-3, TTR>70%) or NOAK in case of AF
- Statins except for non-atherosclerotic strokes (e.g. vessel dissection)
- Compliance to drug prescription >90%

Appendix C

Therapy scores:

Obligatory

Barthel-Index

Berg-Balance-Scale

Timed up and go- Test

Trunk Control Test

FAC

10-m Gait Test

Modified Ashworth-Scale

Aphasia-Check-List

Gugging swallowing Screen (GUSS)

Facultative

Frenchay activity index (to be implemented in KIS)

Motricity index (to be implemented in KIS)

Foot drop screening (to be implemented in KIS)

Spasms Frequency Scale

Pain Numeric Scale

Achner Aphasia- Test

Bogenhauser Dysphagie Score (BODS)