Ischemic Stroke, Obesity and Thrombolysis (ISOT)

Principal Investigator:	PD Dr. med Georg Kägi
Status:	upcoming
Project Start:	2022
Project End:	2022
Trial Design /Class:	multicentric prospective observational study, Category: A
Number of Patient:	750 patients
Centers:	Inselspital Bern, Universitätsklinik Zürich, Kantonsspital Zürich
Sponsor/Partner:	Inselspital Bern
Funding:	Swiss National Foundation

Summary:

All patients receiving thrombolytic treatment for acute ischemic stroke will be included in this study. The decision for treatment and selection of thrombolysis type is allocated to treating stroke physicians who will follow national and international stroke guidelines and considering the clinical and radiological findings. Patients are given either a) intravenous rt-PA, b) endovascular treatment such as intra-arterial urokinase or rt-PA and/or mechanical recanalization techniques, or c) two thirds of the standard dose intravenous rt-PA followed by endovascular treatment such as intra-arterial urokinase or rt-PA and/or mechanical recanalization techniques. Patient involvement in this study will not influence any treatment decision. Patients will undergo a complete diagnostic stroke work-up, including assessment of vascular risk factors and medication, clinical neurological examination using the National Institutes of Health Stroke Scale score on admission and 24h after thrombolysis, laboratory examination, brain and neurovascular imaging, echocardiography and 24-hours ECG to determine stroke etiology using the TOASTcriteria. All patients will be weighed as early as possible, but stringently within 24h after thrombolysis. If they are able to stand at 24h, a standard calibrated licensed scale will be. Otherwise, patients will be weighed on a special bed scale calibrated and validated for the use for patient weighing. In addition, body height, waist and hip circumference of each patient will be measured. All patients will be examined by CT and CTA or MRI and MRA at 24h and in any case of clinical deterioration to exclude intracranial hemorrhage and to assess recanalization in case of vessel occlusion. The treating physician will initiate secondary prevention of stroke as soon as possible and according to current guidelines. Body weight and clinical assessments will be performed by stroke physicians at following visits: I) day 3-5 and/or hospital discharge, II) 3-month and III) 12-month. Patients in whom a clinical follow-up examination is not possible will be evaluated by a structured phone interview.

Objectives:

This study focuses on the relationship between obesity and stroke, which are both characterized by increasing incidence and prevalence with epidemic proportions worldwide and tremendous socio-economic consequences. Furthermore, obesity is an established risk factor for stroke and affects especially younger people, which increases the stroke incidence in younger patients. This prospective study aims to cover the following topics:
I) mortality and outcome in obese patients.
II) safety and clinical outcome of thrombolysis in underweight patients.
III) recanalisation rate of vessel occlusion in obese patients as marker of efficacious thrombolysis.
IV) clinical and radiological outcome of intravenous thrombolysis in comparison to endovascular treatment in obese patients.
V) relationship between waist-to-hip ratio as well as waist circumference and stroke outcome as compared with BMI.
VI) specific causes of death in underweight vs. obese patients.
VII) frequency and type of in-hospital complications in underweight vs. obese patients.
VIII) impact of in-hospital weight loss and nourishment on stroke outcome.
IX) recurrence of stroke and cardiovascular events in underweight vs. obese patients.