Introduction:
Deviations from strict eligibility criteria for intravenous thrombolysis (IVT) in ischemic strokes regarding either license contraindications to alteplase or relative contraindications to thrombolysis have been reported in international literature, with conflicting results on patients’ outcome. The aim of our study was to evaluate safety and efficacy for patients receiving IVT outside standard inclusion criteria.

Methods:
Retrospective analysis of our department’s thrombolysis database. We compared 83 patients with strict protocol adherence (strict protocol group) [mean age 63 years and National Institutes of Health Stroke Scale (NIHSS) at admission 12/range 5–28] and 41 patients with protocol deviations (off-label group) [mean age 68 years and NIHSS at admission 10/range 2–24], in particular 10 patients >80 years old, 13 patients with mild stroke-NIHSS<5, and 22 with symptom-to-needle time 3-4.5 hours (4 patients had 2 deviations).

Results:
Patients in the off-label group were older but had no difference in baseline severity scores (SAPSII, NIHSS). They had no statistically significant difference on short-term (NIHSS at 7 days, need for critical care support, primary adverse event) and long-term (mortality, functional outcome at 3 months) outcome measures when compared to standard protocol patients.

Conclusion:
In accordance with international literature, off-label thrombolysis is safe and equally effective to standard protocol thrombolysis. Thrombolysis strict protocol needs expansion of inclusion criteria.