GBP. All patients were initially escalated up to 400 mg of GBP three times a day.

Results: A dramatic improvement of evident movements occurred following treatment with GBP.

Conclusions: Data makes of GBP an attractive compound for patients with signs of tardive dyskinesia, especially for patients receiving polipharmacotherapy Further studies are warranted.

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P01.17

ADJUNCTIVE AMISULPRIDE TO FLUVOXAMINE IN MAJOR DEPRESSION: EARLY SSRI ONSET OF ACTION

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Objectives: The topic of early response to antidepressant treatment has been extensively studied in Major Depression. We serendipitous observed an increase tolerability and an early onset of antidepressant fluvoxamine activity when associated with amisulpride in patients with Major Depression. The purpose of this study was to investigate our preliminary observations.

Method: A 6-week open trial with the combination of fluvoxamine (100 mg/day) and amisulpride (50 mg/day) on outpatients with DSM-IV diagnostic criteria for Major Depression was carried out. Clinical symptoms were evaluated using the HDRS at baseline and week 1st, 2nd, 3rd, 4th and 6th. HDRS score at T0 was 26.4 +/– 5.2. At T2 all patients presented a lower score than 18. The score at T6 was 8.4 +/– 4.2.

Results: All patients showed a statistically significant improvement ($P < 0.00001$ Freedman analysis of variance) of depressive symptoms. The HDRS item analysis demonstrated that the first therapeutic effect was the disappearance of the sleep depressive pattern at the end of the 1st week. None of the patients expressed significant side effects.

Conclusions: Findings appear to suggest an increased SSRI tolerability and an early onset of fluvoxamine action in association with amisulpride. Further studies are warranted to confirm these results.

P01.18

ROLE OF PRO-INFLAMMATORY CYTOKINES IN DOWN'S SYNDROME

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Objective: Clinical similarities shared by ageing in Down's syndrome (DS) and Alzheimer's disease (AD) found a neuropathological verification in the presence of cerebral β amyloid protein (A β) plaques. The gene coding for the amyloid precursor protein was localised on chromosome 21. Some Authors suggest an hypothetical pathogenic role of pro-inflammatory cytokines in the dementia of Alzheimer type (DAT). The purpose of this study was to investigate the role of pro-inflammatory cytokines in the DS.

Method: The study included 18 institutionalized mental retarded patients with DS (full trisomy) and 18 sex- and age-matched controls with Menial Retardation (MR) cauded by perinatal ischemic cerebral damage. Patients fulfilled DSM-IV diagnostic criteria for MR and were assessed with WAIS. Concomitant psychopathological symptoms were evaluated through the AIRP, SPL CD3, CD19, CD4, CD8, CD3/HLA-DR and total NK were assayed by flow cytometry. IL-6, TNF-α, MIP-1α, MIP-1β and RANTES serum levels were determined by ELISA test.

Results: Cytokine levels in patients with DS were higher than controls. In the DS group there was a statistically significant correlation between IL-6 and the IQ level; MIP-1α and MIP-1β levels inversely related with age and anxiety symptoms but did not correlate with VES. These results were not observed in the control group where MIP-1α and MIP-1β correlated with VES.

Conclusions: Findings appear to suggest an Alzheimer-like implication of the Immune System in the DS cognitive decline. Further longitudinal studies are required.

P01.19

LACK OF EFFECTS OF ST. JOHN'S WORT EXTRACT ON AUTONOMIC AND COGNITIVE FUNCTIONS

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Background: Various extracts of hypericum perforatum (St John's wort) are used as antidepressants in Germany. However their pharmacodynamic properties i. e. the cognitive effects and the tolerability are not well established. Therefore aim of the present study was to investigate the effects of a standardized St. John's wort extract on cognitive and autonomic functions.

Design: A double-blind randomized, placebo controlled cross over trial was performed. 12 healthy male volunteers (age 23–32 years) orally received capsules of St. John's wort extract containing 900 µg hypericin (Helarium Hypericum®) t. i. d. as well as placebo for 14 days each. Parameters of heart rate variability were assessed with the means of a standardized autonomic test battery (PowerLab® system, Australia). In parallel cognitive functions were measured using a computerized test battery (Wiener Test System®). Measurements were performed repeatedly before the start of drug administration and on the last treatment day.

Results: St. John's wort extract did not cause significant changes of heart rate and parameters of heart variability as compared with placebo ($p > 0.05$). In parallel no significant changes of short term memory, reaction time, subjective mood, psychomotor ability and performance in the Stroop test were observed.

Conclusions: In the present study no evidence for a relevant central and/or peripheral pharmacodynamic action of standardized hypericum extract could be found. The clinical implications of the negative findings and their impact on the risk-benefit ratio of the herbal drug remain to be determined in long term studies.

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