



Anticonvulsive activity according to DCTC and DTE values is higher than control at 1.8–2.8 and 1.8–2.4 times, respectively. The maximal activity of studied esters is detected 3 hours after administration.

P.3.035 The profile of anti-anxiety action of tofisopam in the treatment of generalized anxiety disorder

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Statement of the study: Tofisopam, which belongs to 2,3-benzodiazepines, i.e., homophthalazines, seems to have different mechanisms of action than other benzodiazepines, although they still remain unrevealed. Their anxiolytic properties are related to their specific binding to the basal ganglia (Horvath et al. 2000). Results of multicenter, randomized, double blind comparison of tofisopam (150 mg/d) and hydroxyzine (75 mg/d) in a group of 51 patients, with generalized anxiety disorder, indicated the same reduction of anxiety symptoms measured by Hamilton Anxiety Rating Scale after 2 weeks and after 6 weeks of treatment. In the study of Kokoszka and Bryła (2004) 66 patients, aged 19–74 $M=41.4$ $DS\ 13.2$ with generalized anxiety disorders were randomized for two weeks of the treatment of tofisopam (50 mg three times a day), diazepam (5 mg three times a day), or placebo group. The mean decrease in Hamilton Anxiety Rating Scale score was significantly higher than in placebo group both in tofisopam ($p < 0.001$) and diazepam group ($p < 0.001$). This paper is aiming at the presentation of the data on profile of the action of tofisopam found in this study.

Methods: The anxiety symptoms were measured with items of Hamilton Anxiety Rating Scale, whereas other neurotic symptoms were measured with the self-rating symptoms check list S-II (Aleksandrowicz, 2000), a Polish derivative of Derogatis SCL-90, that measures subjective experiencing of symptoms by patients.

Results: The mean decrease of symptoms in S-II list was statistically significantly higher in the tofisopam than placebo group ($M=87.6$ versus 38.6 ; $t=-2.16$, $p < 0.005$) and there was no statistically significant difference between

tofisopam and diazepam groups ($M=87.6$ versus 81.7 ; $t=0.22$, $p > 0.80$).

After two weeks of treatment with tofisopam statistically significant changes in Wilcoxon's test were found in:

Items of HARS

- At $p < 0.001$: anxiety, tension, intellectual, respiratory, cardiovascular symptoms
- At $p < 0.004$: depressed mood
- At $p < 0.005$: fears, insomnia
- At $p < 0.002$: autonomic symptoms and behavior at interview
- At $p < 0.05$: gastrointestinal symptoms

Items of S-II

- At $p < 0.001$: dystymia
- At $p < 0.002$: anxiety, insomnia
- At $p < 0.003$: somatic, intellectual dysfunctions
- At $p < 0.05$: social dysfunctions, dissociatio

Conclusions: Tofisopam is effective in the treatment of a wide variety of symptoms related to anxiety. In the self-report scale tofisopam was similarly effective as diazepam and statistically more effective than placebo.

References

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P.3.036 Novel anxiolytic Selank: results of the Phase II clinical trials

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One of the recent trends in the design of novel psychotropic medicines is creation of anxiolytics on the basis of an endogenous neuropeptide structure. During long-term fundamental research at Zakusov State Institute of Pharmacology and the Institute of Molecular Genetics an original synthetic heptapeptide derivative of taftsin, Selank, was developed. Experimental study of Selank