

## **A randomized, double-blind multicenter comparison of a herbal preparation STW-5 with cisapride in the treatment of dysmotility type of functional dyspepsia**

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The prokinetic drug cisapride, considered as standard treatment for dysmotility type of functional dyspepsia, is withdrawn from market. Therefore efficacious alternatives are strongly needed. Motility regulating properties on gastrointestinal smooth muscles have been determined for the herbal preparation STW-5\*, containing an alcoholic fresh plant extract from *Iberis arriara* and eight other plant extracts. In the present study, non-inferiority of STW-5 to cisapride and a developmental preparation STW-5-II for treatment of dysmotility type of functional dyspepsia was hypothesized. Main outcome variable of this double-blind, double dummy, multicentric study was the improvement of a gastrointestinal symptom score (GIS). After a standardized diagnostic work-up and one-week of wash-out, 186 patients were randomized to one of three treatment regimens, applied three times daily for four weeks. Dyspeptic symptoms were assessed at baseline, after two and four weeks and after 6 months follow-up. 183 patients had at least one control examination of GIS (intention to treat collective). 137 patients remained in the per protocol group (PP). All treatment regimens were well tolerated. Mean value of GIS for the PP collective at beginning of treatment was 14.5, 14.3 and 14.4 in the cisapride-, STW-5- and STW-5-II group respectively and decreased to 3,6, 2,3 and 2,8 respectively, after four weeks of treatment. This improvement of GIS was statistically significant for all three treatment regimens ( $p < 0,0001$ ). There was no statistically significant difference between the efficacy of cisapride, STW-5 and STW-5-II in the investigated indication ( $p < 0,001$ ). Conclusively, the results of this study suggest that the herbal preparation STW-5 is an efficacious alternative for cisapride in the treatment of dysmotility type of functional dyspepsia.

\* *Iberogast*