First clinical data of a natural immunomodulator in colorectal cancer

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Background. MSC (trade-name AVEMAR®) is a per os applicable complex of multiple, biologically active molecules obtained from fermented wheat-germ extract. Preclinical studies suggest a potent antimetastatic activity and a favorable toxicity profile. On a pilot-scale, this phase II clinical study was aimed to find out whether or not MSC as a support to surgery or plus chemotherapy adds any therapeutic benefit compared to the same combination without MSC in colorectal cancer.

Materials and methods. From 1998 to June 1999, 18 control patients and 12 consecutive colorectal cancer patients were enrolled into this study. All patients underwent curative surgery. The control group (18 patients) received no other therapy or adjuvant chemotherapy alone. The MSC group (12 patients) received MSC alone or plus adjuvant chemotherapy. Until now, the median follow-up has been 9 months.

Results. The interim data of the study provide evidence that, in the MSC group, no new metastases, neither hepatic nor other, have occurred so far. On the contrary, several new metastases have developed in the control group.

Conclusion. Orally administered MSC is a potent candidate to be regarded as a supportive therapy to surgery or plus chemotherapy for colorectal cancer patients.

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