

Table 1. Controlled clinical trials of fermented wheat germ extract (FWGE) for cancer

Source: Alexander Kalisch, Markus Horneber, CAM-Cancer Consortium. Fermented wheat germ extract [online document]. January, 2019.

| Study | Methods | Participants | Interventions | Results | Comments | | | |
|---|---|--|---|--|--|--|--|--|
| Randomized controlled trials | | | | | | | | |
| Demidov 2008 (4) | 2-arm, randomized, open label, parallel | 58 patients with malignant melanoma (stage III) | Darcarbazine with or without FWGE | Improved survival rates and progression free survival after seven years of follow up in the FWGE group | Small study with high risk of selection bias | | | |
| Prospective, non-randomized controlled trials | | | | | | | | |
| Jakab 2003 (5) | 2-arm, prospective, non- randomized, open-label, parallel | 176 patients with colorectal cancer | Oncological therapy (radio- and/or chemotherapy) with or without FWGE | Reduced metastases, higher overall survival rates and longer progression free survival in the FWGE group | Study with high risk of selection bias | | | |
| Sukkar 2008 (6) | 2-arm, prospective, non- randomized, open label, parallel | 55 patients diagnosed with head and neck cancer (stage IIIa, IIIb and IV) | Oncological therapy (surgery, radio- and/or chemotherapy) with or without FWGE | Significantly better quality of life in the FWGE group | Small study with high risk of selection and detection bias low reporting quality. | | | |
| Garami 2004 (18) | 2-arm, prospective, non- randomized, controlled, open label, parallel | 22 children with various tumours | Different chemotherapy regimen with or without FWGE | Significantly reduced incidence of neutropenic fever in the FWGE group | Small study with high risk of selection bias. Low reporting quality. | | | |
| Barabàs 2006 (3) | 2-arm, prospective, parallel | 45 patients diagnosed with head and neck cancer (UICC stage II and III) | Oncological therapy (surgery, radio- and/or chemotherapy) with or without FWGE | Significantly fewer local relapses and fewer progression events in the FWGE group | Small study with high risk of selection and detection bias. Low reporting quality. | | | |

| Trials with unclear design | | | | | | | | | |
|----------------------------|------------------------|--|---|---|--|--|--|--|--|
| Balogh 1999 (17) | No further information | 55 women with breast cancer (UICC stage I – IV) | Besides the intake of FWGE no other treatment published | Significantly better quality of life in the FWGE group | Unpublished study data. Due to very little information on methods, participants, treatments and results available no valid conclusion is possible. | | | | |
| Balogh 1999 (17) | No further information | 39 women with breast cancer (UICC I – IV) | Chemotherapy with FWGE | Significantly less side effects with FWGE | Unpublished study data. Due to very little information on methods, participants, treatments and results available no valid conclusion is possible. | | | | |
| Hidvegi 2003 (19) | No further information | 16 patients with small cell and adeno lung cancer (advanced stage) | Chemo- and/or radiotherapy with FWGE | Significant improvement of global state of health and fatigue | Unpublished study data. Due to very little information on methods, participants, treatments and results available no valid conclusion is possible. | | | | |