

Criteria for the assessment of the methodological quality of the mistletoe studies [1-4]

Prospective comparison studies (parallel group design)

- A Protection against selection bias, especially by adequate randomisation
- B Minimisation of the heterogeneity by pre-stratification or matching
- C Protection against observer bias by blinding of the patient, care provider and outcome assessors
- D Protection against performance (treatment) bias by standardisation of care protocol, documentation of all co-interventions, blinding of patients and care providers
- E Protection against measurement (detection) bias by standardisation of outcome assessment
- F Protection against attrition (exclusion) bias: attrition rate < 10%, or intention-to-treat and per-protocol analysis in combination with sensitivity analysis, and comparison of prognostic characteristics of lost patients and compliers
- G Outcome measure relevant and well described
- H Intervention, patient characteristics, disease (diagnosis, stage, duration), and previous therapy well described
- I Study design well described
- J Results well described
- K Data quality assured by GCP-ICH guidelines, especially by monitoring

Cohort studies with before-after design (no comparison group)

- L Prospective: +, retrospective: -, unclear: ?
- M Patients, diagnosis, and prognostic factors well described
- N Outcome measures relevant and well described
- O Intervention well described
- P Concomitant therapies described
- Q Before-after changes clearly described, temporal coincidence to the intervention clear
- S Patient selection can be excluded

Retrospective comparison studies (parallel group design)

- Comparison valid, i.e. bias in favour of mistletoe excluded?: + yes, (+) partial, - no.

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References

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- [2] Kienle, G. S. and H. Kiene, Die Mistel in der Onkologie - Fakten und konzeptionelle Grundlagen, Schattauer Verlag, Stuttgart, New York 2003.
- [3] Kienle, G. S., Kiene, H. and Albonico, H. U. Health Technology Assessment Report: Anthroposophic Medicine. Complimentary Medicine Evaluation Program (PEK) of the Swiss Federal Office for Public Health. Download: www.ifaemm.de. 2005.
- [4] Kienle, G. S., H. Kiene and H. U. Anthroposophic Medicine: Effectiveness, Utility, Costs, Safety. Stuttgart, New York: Schattauer Verlag, 2006.