



Title	MedicLaser +TinniTool®
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Reference	Technology Review Report, 010/2009. http://medicaldev.moh.gov.my/uploads/tr_2009/tinnitool.pdf

Aim

To determine the safety, effectiveness, and cost effectiveness of MedicLaser + TinniTool®.

Conclusions and results

The product is CE marked. However, there was no retrievable evidence on its clinical safety. This review includes only two studies (RCT), but a contradiction was found between the studies in analyzing the mean of delta Tinnitus Handicap Inventory scores in both the experimental group and the control group. Hence, the evidence on effectiveness was inconclusive. There was no retrievable evidence on cost effectiveness.

Recommendations

The device is not recommended for routine use. However, it can be considered for use as a research tool to produce more evidence on its clinical safety and effectiveness.

Methods

Electronic databases, which included MEDLINE, EMBASE, and Horizon Scanning were searched, as were the websites of the manufacturer, the European Commission's Medical Devices Sector, and the Food and Drug Administration. The Malaysian agency for devices was contacted for relevant regulatory affair certificates. Finally, a manual literature search was conducted via the manufacturer's list of literature. No limits were placed on the search. All published clinical trials were included. Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) and evidence was graded using US/Canadian Preventive Services Task Force.

Further research/reviews required

More clinical trials are warranted.