Reviewer's report

Title: Phase II trial of daily low-dose nedaplatin and continuous 5-fluorouracil infusion combined with radiation for the treatment of esophageal squamous cell carcinoma

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Reviewer: Ate van der Gaast

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This is a small phase II trial with radiotherapy combined with daily low dose nedaplatin and continuous 5FU for patients with squamous cell carcinoma of the esophagus. This trial had a slow accrual and a total of 33 patients were included over a period of 5 years. What was the primary objective of this study and what was the power calculation?

In 31 patients the radiotherapy doses range from 50.4 to 66 Gy. What was the reason for this variation and was this specified in the study protocol? Two patients received a combination of external radiotherapy and brachytherapy. This is an essential different treatment? Was this according to the protocol? Although this is acknowledged by the authors it is not clear what were the reasons for this variation. Besides the total dose and dose fraction details about how the radiotherapy was delivered are lacking.

About 12 patients had “early” disease (stage I and II) and 3 patients had distant metastases (stage IVB). Why were patients with distant metastases included in this trial? Were there any restriction for the field margins? Had all patients EUS or were there also a number of patients with no pass?

Response evaluation after chemoradiotherapy is often not very reliable this is not discussed by the authors. Were all complete responses biopsy proven?

27.3% of the patients did not receive planned treatment. What was the actual delivered treatment in these patients.

What was the median and minimum follow-up in these patients? The survival curves suggest that more than 50% of the patients were censored before 24 months.

A number of patients received additional chemotherapy. The authors state that additional chemotherapy did not significantly influence survival. However one should realize that the total numbers were very small.

In the conclusion the authors stat that daily low dose nedaplatin and continuous 5-FU infusion combined with radiotherapy is tolerable and may yield a higher CR rate and better survival for patients with esophageal squamous cell carcinoma. What is the definition of tolerable since 27.3% of the patients did not receive the planned treatment. Whether a treatment results in a higher response rate and/or survival can only be assessed in a randomized trial.
Level of interest: An article of insufficient interest to warrant publication in a scientific/medical journal

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests