Author’s response to reviews

Title: Dexamethasone for the prevention of a pain flare after palliative radiotherapy for painful bone metastases: a multicenter double-blind placebo-controlled randomized trial

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Author’s response to reviews: see over
Dear sir/madam,

I hereby send you our manuscript entitled “Dexamethasone for the prevention of a pain flare after palliative radiotherapy for painful bone metastases: a multicenter double-blind placebo-controlled randomized trial”, to be considered for publication in “BMC Cancer”.

In the revised manuscript, we added line numbering, since we forgot to number the lines in our initial manuscript.

Radiotherapy for palliation of painful bone metastases has a response rate of more than 60%. However, a side-effect from radiotherapy is a temporary increase in pain, the so-called pain flare. This pain flare occurs in approximately 40% of patients and has a negative impact on quality of life. It is thought to be caused by periostal edema. Dexamethasone might reduce this edema.

This manuscript describes the background and study design of our multicenter double-blind placebo-controlled randomized trial. The purpose of this trial is to study the effectiveness of dexamethasone to prevent a pain flare after palliative radiotherapy for painful bone metastases and to determine the optimal dose schedule. So far, 134 patients of the 411 patients required have been included. Since the risks of the study using dexamethasone are considered minimal, an interim analysis will not be performed.

No randomized trials have been published that investigated the effect of dexamethasone in prevention of a pain flare after palliative radiotherapy for painful bone metastases.

The trial follows the CONSORT guidelines and is registered at ClinicalTrials.gov (NCT01669499). The trial receives funding from the Dutch Cancer Society (grant no. UU 2009-4595) and ZonMw, a Dutch organization for health research and innovation of healthcare (grant no.11510009). The study protocol was approved by the Medical Ethics Committees. Proof of funding and ethics are provided as attachments.

All authors have read and approved the manuscript. On behalf of all authors, I state that there are no conflicts of interest and no financial disclosures. This manuscript is not under consideration elsewhere.

I hope you will consider this manuscript suitable for publication in your journal. If necessary, I can provide you with supplementary information.

Looking forward to your reply,

Yours sincerely,

Paulien Westhoff, M.D.

Attachments:
Proof of funding Dutch Cancer Society (grant no. UU 2009-4595)
Proof of funding ZonMW (grant no.11510009)
Proof of ethics (letter in Dutch, last paragraph in English)