Author's response to reviews

**Title:** Safety and hemostatic efficacy of fibrin pad in partial nephrectomy: Results of an open label Phase I and a randomized, standard-of-care-controlled Phase I/II study

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**Author's response to reviews:** see over
To
Dr Henderson
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Subject: Re-submission of manuscript (MS: 4135873367507093) entitled “Safety and hemostatic efficacy of fibrin pad in partial nephrectomy: Results of an open-label Phase I and a randomized, standard-of-care-controlled Phase I/II study”

Dear Dr Henderson:

Thank you for your suggestion for our manuscript (MS: 4135873367507093) entitled “Safety and hemostatic efficacy of fibrin pad in partial nephrectomy: Results of an open-label Phase I and a randomized, standard-of-care-controlled Phase I/II study”. We have made the suggested revision, and are resubmitting the manuscript for possible publication as an original article in BMC Nephrology.

The revision is as follows:

Query

Ethical Approval

We not in your manuscript that you state both studies were conducted in Israel in accordance with the requirements for conduct of clinical studies (Ministry of Health, Good Clinical Practice Standard), ICH Harmonised Tripartite Guideline for Good Clinical Practice (2000), and the Declaration of Helsinki (1996). However, can you please provide further clarification whether ethical approval was obtained for your study? Can you please include the full name of the ethical committee that granted approval in the Methods section of your manuscript.

If your study was exempt from requiring ethical approval, can you please also confirm this in your revised manuscript. Would you also be able to provide documentary evidence from your institutional or regional ethics committee that confirm that your study is exempt.

Response

Ethics committee approvals were obtained for both the studies and this information has been included in the manuscript in the first paragraph of the methods section, and reads as follows:

Both studies were conducted in Israel in accordance with the requirements for conduct of clinical studies (Ministry of Health, Good Clinical Practice Standard), ICH Harmonised
Tripartite Guideline for Good Clinical Practice (2000), and the Declaration of Helsinki (1996). The protocols for the studies were approved by Beilinson Hospital, Rabin Medical Center (Petah Tikva) and Bnei Zion Medical Center (Haifa) ethics committees. All patients provided written informed consent before study participation.

We look forward to your feedback.

Sincerely,

Dr James C. Hart

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