



SDI Review Form 1.6

PART 1:

Journal Name:	<u>International Journal of Biochemistry Research & Review</u>
Manuscript Number:	2013_IJBcRR_4210
Title of the Manuscript:	NERIDRONIC ACID EFFECTS IN POSTMENOPAUSAL OSTEOPOROSIS: TREAT AND ADHERE ANYWAYS
Type of the Article	Research paper

General guideline for Peer Review process is available in this link:

(<http://www.sciencedomain.org/page.php?id=sdi-general-editorial-policy#Peer-Review-Guideline>)

- This form has total 7 parts. Kindly note that you should use all the parts of this review form.



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PART 2: Review Comments

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<u>Compulsory</u> REVISION comments	1- <i>Patients and methods line 76:</i> "....All patients received also 100 mg NER IV bimonthly for the first 18 months, infused in a 0.9% saline solution over the course of 150 min. " <u>Reviewer's questions:</u> a- the authors must add the volume of saline solution used b- the authors should explain why a 100 mg bimonthly dose was used. Actually, in the study of Braga et al. (reference n. 9) the dose used was half (50 mg bimonthly) and the 100 mg dose is usually administered in Paget's Disease of Bone (only 2 infusions) or in Osteogenesis Imperfecta (but only every 3 months). <u>2- Results: lines 89-93:</u> ".... mean lumbar BMD was significantly increased (mean T score -2.8 ± 1.2 at baseline vs. -2.6 ± 1.4 at 18 months, $p < 0.01$)..... <u>Reviewer's request:</u> The results cannot be reported as comparison of the averages of T-scores in the studied population, they must be reported as percent changes from baseline at the different times of the observation. It would be interesting as well to evaluate the percent changes in BMD since the beginning of intramuscular route of administration. <u>3. Discussion: lines 113-114:</u> "...the lack of radiographic evidence of vertebral fractures suggest that this administration regimen for NER may reduce vertebral	



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	fractures “ <u>Reviewer’s Comment:</u> This is a non controlled study therefore it’s not possible to estimate the effect on fracture risk. <i>4-Discussion : lines 127-130: “..this study provides the first data on the efficacy and safety of NER in patients with postmenopausal osteoporosis ...”</i> <u>Reviewer’s Comment:</u> The study of Braga et al (reference 9) including 78 postmenopausal women evaluated the efficacy and safety of IV NER in 2003 while the study of Adami et al (reference 16) including 188 postmenopausal women evaluated the efficacy and safety of IM NER with clinical placebo controlled trials. Cascella et al (Effects of neridronate treatment in elderly women with osteoporosis. <i>J Endocrinol Invest.</i> 2005;28(3): 202–208.) evaluated the efficacy of intramuscular NER too (not cited). Hence the study reported in this manuscript in not “the first”.	
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Minor REVISION comments		
Optional/General comments	This is a non controlled clinical trial on the densitometric effects of neridronate in postmenopausal osteoporosis. In the manuscript are collected data regarding 164 patients affected by gastric or esophageal conditions contraindicating oral bisphosphonates. Other 3 controlled clinical studies have already evaluated the effects of EV and IM administration of neridronate. In this case the interest concerns the subsequent different routes of administration. The Authors must perform a more rigorous statistical analysis and emphasize the fact that the study is "not placebo controlled".	

Note: Anonymous Reviewer