Author’s response to reviews

Title: FimAsartaN proTeinuriA SusTaIned reduCtion in comparison with losartan in diabetic chronic kidney disease (FANTASTIC) : study protocol for randomized controlled trial

Authors:
Jang-Young Kim (kimjy@yonsei.ac.kr)
Jung-Woo Son (soneycar@gmail.com)
Sungha Park (shpark0530@yuhs.ac)
Tea-Hyun Yoo (yoosy0316@yuhs.ac)
Yong-Jin Kim (kimdamas@snu.ac.kr)
Dong-Ryeol Ryu (drryu@ewha.ac.kr)
Ho Jun Chin (mednep@snubh.org)

Version: 2 Date: 03 Dec 2017

Author’s response to reviews:

Editorial requests:

Comment 1) Background section should end with specific objectives or specific hypotheses in PICOS format.

P= patient, problem or population
I = Intervention
C= Comparison
O = Outcome
S = Study design

In CKD patients, fimarsartan compared with losartan renal outcome in 24 weeks and 12

Response 1)

In response, we corrected the sentence in background section as follows.
“Thus, the purpose of the present study, FimAsartaN proTeinuriA SusTaIned reduCtion in comparison with losartan in diabetic chronic kidney disease (FANTASTIC) trial, is to investigate the renoprotective effect of fimasartan in comparison with losartan in patients with in diabetic chronic kidney disease a group and we also aim to evaluate long term effect of strict SBP control on renal and cardiovascular outcomes in comparison with standard SBP control. “

Comment 2) Study design description should include allocation ratio.

Response 2)

In 2.2.3. Randomization section of original manuscript and revision manuscript, we already described allocation ratio. However, we did not describe allocation ratio in abstract.

In response, we corrected the sentence in method of abstract as follows.

Participants were randomized into four groups (1:1:1:1): fimasartan standard SBP control (SBP <140mmHg); fimasartan strict SBP control (SBP <130mmHg); losartan standard SBP control; and losartan strict SBP control

Comment 3) Study design reporting should include framework: non-inferiority?

Response 3)

In response, we corrected the sentence as follows in Method of abstract and in Discussion section

Method of abstract

“This study is a prospective, phase III, randomized, double-blind, active-controlled, non-inferiority, 4-parallel group, dose-titration, multicenter trial.”

In discussion section,

“This was a randomized, double-blind, active-controlled, non-inferiority, 4-parallel group, dose-titration, multicenter study that….”

Comment 4) The study is reported as it had already ended. For the parts where it is necessary, the authors should conjugate the verbs in a future tense, especially in the Methods section.

Response 4)

In response, We all corrected the verbs in a future tense
Reviewer #2:

Comment 1) Background second paragraph line 33, full stop after "CKD [6-8]"

Response 1)

In response, we corrected the sentence as follows

“….CKD [6-8],” → “…..CKD [6-8].”

Comment 2) Section 2.9, explain abbreviation "EDC" in line 31, and also CRA in line 48 and CRC in line 50.

Response 2)

In response, we corrected the sentence as follows

“… is given each EDC (Electronic Data Capture)’s role.”

“… are generated by CRA (Clinical Research Associates) or..”

Comment 3) Last paragraph in the discussion section, I am not sure if the comment on the SPRINT trail regarding strict BP control is correct or I may have misunderstood.

Response 3)

The more detailed comment of SPRINT trial in the last paragraph of the discussion section is as follow.

Although strict BP control had a beneficial outcome in SPRINT trial involving about 28% CKD, the effect of strict BP control on hypertensive diabetic CKD with overt proteinuria could not be determined, because diabetes and overt proteinuria were excluded from study population.