Reviewer's report

Title: Yukmijihwang-tang for the treatment of xerostomia in the elderly: study protocol for a randomized, double-blind, placebo-controlled, 2-center trial

Version: 2 Date: 17 June 2013

Reviewer: Cindy Cooper

Reviewer's report:

Major Compulsory Revisions

The protocol is clear and provided in sufficient detail to allow reproduction. However, the safety monitoring is either insufficient or not well documented. Currently the safety monitoring is limited to blood tests at 8 weeks. There appears to be no adverse event or serious adverse event (SAE) monitoring or reporting until the end of the intervention period.

Within the section labelled 'Safety' there is the following statement:

"Throughout the present study, we will also check whether the 8-week administration of YMJ in xerostomia patients is safe by using these tests or CRF documentations."

However, there is no detail of how this will be achieved.

Authors should have procedures to identify SAEs and these need to be documented in the protocol.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

'I declare that I have no competing interests'