Reviewer's report

**Title:** Quinolone Prophylaxis for the Prevention of BK Virus Infection in Kidney Transplantation: Study Protocol for a Pilot Randomized Controlled Trial

**Version:** 2  **Date:** 8 May 2013

**Reviewer:** Ilkka Helanterä

**Reviewer's report:**

This manuscript by Humar et al describes a study protocol for a pilot randomized controlled trial to assess the safety and efficacy of a 3-month course of levofloxacin to prevent BK virus replication after kidney transplantation.

The manuscript is clear and concise, and adequately describes the study protocol in sufficient detail. The subject is important and the study setting is very interesting. The results will greatly improve our understanding of the efficacy of quinolones against BK virus infections, which is currently unknown in vivo. The study protocol is well designed, and seems adequately powered for a pilot study. The statistics seems adequate.

I have only minor comments:

1. In the introduction, the authors describe the prognosis of BKV nephropathy to be poor (average transplant failure rate 46%, up to 100%). This is probably true in older patient series, but in the very recent years, much better outcome has been reported (such as Schaub et al, AJT 2010, among others). This could be discussed.

2. The reference to the randomized controlled trial published in 1980 is missing (introduction, paragraph 2).

3. BK viruria is quite commonly seen also in healthy nonimmunosuppressed individuals, but with lower urinary viral load. So, some patients might excrete BKV in the urine already before or at the time of transplantation from native kidneys. This could be discussed, as it may have an impact on the sensitivity of this study to detect changes in the primary endpoint (time to viruria). Therefore it is important that the viral load in urine and BK viremia are measured as well (in this protocol as secondary clinical outcomes).

4. Under the subheading "trial intervention", a reference number "72" is given, this is probably a mistake?

5. Under the subheading "Outcome measures": "Participants who take at least 80% of study medication and do not report any episodes of non-adherence will be classified as adherent". How is the frequency of taking the study medication measured?

**Level of interest:** An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests