

**Table 2: Protocol version and amendments – Date and version identifier.**

<b>Issue date:</b> 2013-July-12 <b>Authors:</b> MN; JC; ELM	Original protocol version.
<b>Issue date:</b> 2015-04-24 <b>Authors:</b> MN; JC; ELM	Amendment 06: Because of preliminary analysis showing a higher dropout rate than expected, the number of planned included patients is raised from 250 to 288. Therefore the trial is also extended until July 2016.
<b>Issue date:</b> 2015-08-11 <b>Authors:</b> MN; JC; ELM	Amendment 07: Cf. amendment 06, a higher number is being included. Because of fewer patients belonging to one specific stratification group (men with a HTQ score>3.2) were included in the trial, the inclusion period is extended until September 2015 and the number of maximal included patients is raised to 340. This ensures a big enough number of the mentioned stratification group being included, in order later to be able to make statistically sound analysis.