A thorough QT study in healthy volunteers - design and analysis

The International Conference of Harmonization has bundled a discussion about the principles to be applied in a study dedicated to the proarrhythmic potential of non-antiarrhythmic drugs. While this discussion was still ongoing, a phase I study was designed at Schering AG to investigate potential QT-prolonging effects of a compound currently under development. We present the study in view of the scientific discussion, including design, different heart rate correction methods, planned evaluations, and key results.

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