Appendix 1

Sample size calculation

For assessing non-inferiority in paired proportions we will use an asymptomatic test statistic, which is the so-called Nam score test, or restricted maximum likelihood estimation (RMLE-based) test statistic.(1) The power and sample size was calculated in the statistical software package PASS (Power Analysis and Sample Size), verified for non-inferiority tests (one-sided) for two correlated proportions.(2) The calculations were checked by a statistician (the power formula is given in the PASS User’s Guide).

We set the following parameters in PASS based on consensus discussion by the clinicians in our study team and a comprehensive review of the aforementioned literature:

- **Power** is the probability of rejecting a false null hypothesis. Set at 0.80.
- **Equivalence Difference (De)** is the maximum difference between the two proportions that is still called 'equivalent.' Set at 0.05 (equal to the non-inferiority margin).
- **Actual Difference (Da)** is the actual difference between Pt and Ps. That is, Da = Pt - Ps. Set at 0.03.
- **Treatment Proportion (Pt )** is the response proportion to the treatment (experimental or new) test. Set at 0.89.
- **Standard Proportion (Ps)** is the response proportion to the standard (reference or old) test. Set at 0.86.
- **The Nuisance Parameter** is a value that is needed, but is not a direct part of the hypothesis. The parameter is based on the proportion of discordant pairs. Set at 0.12.
- **Alpha (α)** is the probability of rejecting a true null hypothesis. Set at 0.05.
- **Beta (β)** is the probability of accepting a false null hypothesis. Set at 0.20

References