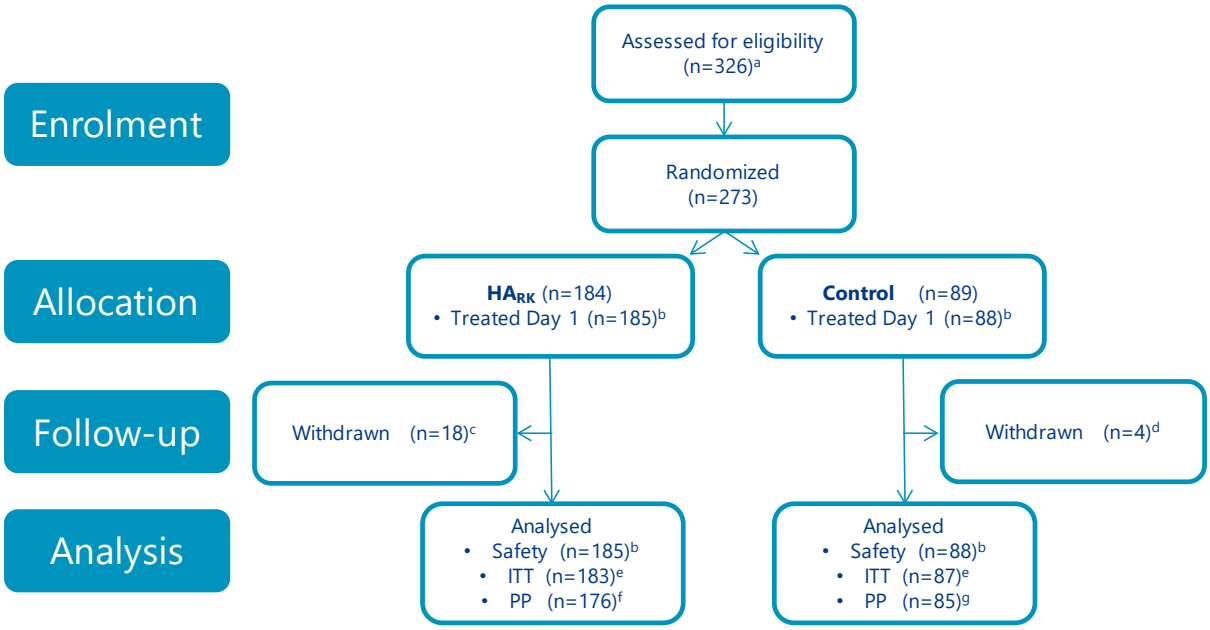
Supplemental Digital Content 1, Figure, Subject disposition



ITT: Intention-to-treat, PP: Per protocol

[a] 53 subjects were not randomized (did not meet eligibility criteria [n=50]; other reason [n=3])

[b] 1 subject was randomized to control at baseline, but erroneously received HA_{RK}. For analysis purposes, this subject is included in the control group in the ITT population (as per the as-randomized principle), and in the HA_{RK} group in the safety population (as per the as-treated principle).

[c] Lost to follow-up (n=10); withdrew consent (n=8)

[d] Other reason (n=2); lost to follow-up (n=1); withdrew consent (n=1)

[e] 1 subject in the HA_{RK} group and 2 subjects in the control group had MLFS score 5 at baseline, and were thus excluded from the ITT population

[f] 8 subjects were excluded from the HA_{RK} PP population because they were excluded from the ITT population (n=1[e]), or because of withdrawal of consent prior to Week 8 (n=1) or protocol deviations (missed Week 8 visit or effectiveness evaluation [n=4]; not treated in both lips at baseline [n=1]; wrong study product used at touch-up [n=1])

[g] 4 subjects were excluded from the control PP population because they were excluded from the ITT population (n=2[e]), or because of withdrawal of consent prior to Week 8 (n=1) or protocol deviations (wrong study product used at baseline [n=1])