Supplementary Online Content

eTable. Subgroup Analyses Stratified by Nugent Score

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable. Subgroup Analyses Stratified by Nugent Score

Nugent BV+

Visit	Dequalinium chloride n[a]/N[b] (%)	Metronidazole n[a]/N[b] (%)	Treatment difference (95% CI[c])	p-value
Visit 1 (ITT[d])	35/37 (94.6)	36/40 (90.0)	4.6 (-10.2, 19.4)	0.004
Visit 1 (PP[e])	29/30 (96.7)	25/29 (86.2)	10.5 (-6.9, 27.8)	0.002
Visit 2 (ITT[d])	28/37 (75.7)	36/39 (92.3)	-16.6 (-32.7, -0.6)	0.57

Nugent Intermediate

Visit	Dequalinium chloride n[a]/N[b] (%)	Metronidazole n[a]/N[b] (%)	Treatment difference (95% CI[c])	p-value
Visit 1 (ITT[d])	13/15 (86.7)	10/10 (100)	-13.3 (-31.4, 4.7)	0.42
Visit 2 (ITT[d])	13/15 (86.7)	5/8 (62.5)	24.2 (-10.5, 58.9)	0.01

Nugent Normal

Visit	Dequalinium chloride n[a]/N[b] (%)	Metronidazole n[a]/N[b] (%)	Treatment difference (95% CI[c])	p-value
Visit 1 (ITT[d])	16/17 (94.1)	22/23 (95.7)	-1.5 (-20.9, 17.8)	0.08
Visit 2 (ITT[d])	14/17 (82.4)	20/23 (87.0)	-4.6 (-28.7, 19.5)	0.19

The Nugent BV+ subgroup would correspond to the modified intention-to-treat, the original primary efficacy population before the protocol amendment. The analyses at Visit 1 would correspond to the primary endpoint and are therefore presented using the intention-to-treat and per-protocol populations. The rest of the analyses are presented using only the intention-to-treat population.

Visit 1= 7-11 days after treatment start, Visit 2= 20-40 days after treatment start
[a]n= number of cured
[b]N= number of patients in the respective treatment arm with non-missing values
[c]CI= confidence interval
[d]ITT= intention to treat
[e]PP= per protocol

CI and p-value based on Farrington-Manning test with a one-sided α= 0.025 and a non-inferiority margin of 15%