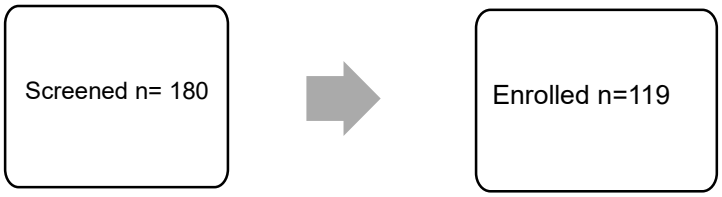
Study Title: Multicentric, randomized, comparative clinical study on the evaluation of the efficacy and safety of Neovis® Total Multi versus Systane® Balance on the treatment of ocular dryness associated with meibomian gland dysfunction

1. Participants



2. Primary Outcome Measure:

Table 01: TBUT total scores at both D0 visit and D28 visit on worse eye – PP population

		Neovis Total Multi N=52	Systane Balance N=55	Total N=107
TBUT score of worse eye at D0 visit	N	52	55	107
	Missing	0	0	0
	Mean ± SD	**9.6 ± 2.8**	**9.6 ± 2.9**	**9.6 ± 2.8**
	Median	10	10	10
	Q1; Q3	8 ; 12	7 ; 12	7 ; 12
	Min Max	1 ; 15	2 ; 15	1 ; 15
TBUT score of worse eye at D28 visit	N	52	55	107
	Missing	0	0	0
	Mean ± SD	**13.9 ± 6.0**	**14.7 ± 6.1**	**14.3 ± 6.1**
	Median	13	15	14
	Q1 ;Q3	11 ; 16	11 ; 17	11 ; 16
	Min Max	3 ; 35	5 ; 44	3 ; 44

Table 02 :Change of the TBUT total score between D0 and D28 on worse eye - PP population

		Neovis Total Multi N=52	Systane Balance N=55	Total N=107
Change of TBUT on Worse Eye from baseline	N	52	55	107
	Missing	0	0	0
	Mean ± SD	**4.3 ± 4.7**	**5.2 ± 5.1**	**4.8 ± 4.9**
	95% CI	3.0 ; 5.6	3.8 ; 6.6	3.8 ; 5.7
	Median	3	4	4
	Q1; Q3	1 ; 6	2 ; 7	2 ; 6
	Min Max	-3 ; 20	-1 ; 30	-3 ; 30

Table 03 :Result of the non-inferiority analysis - PP population

Population	Neovis Total Multi	Systane Balance	Difference Neovis - Systane	95% CI	P Non inferiority (Unilateral test)
Day 0 (baseline) mean (SD)	9.58 (2.8)	9.51 (2.85)	-	-	-
Day 28 mean (SD)	13.88 (6.04)	14.69 (6.12)	-	-	-
Adjusted change between Day 0 and Day 28 - LSM (SEM)	4.3 *(0.67)	5.19 *(0.65)	-0.90	[-2.75 ** ; 0.96]	0.498

3. Adverse Events:

No AE related to the study products or method was reported in Neovis Total Multi group.
In Systane Balance group, two AEs related to the study products or method were reported for the same subject (S03-501): one conjunctival hyperaemia, possibly related to Systane Balance and one eyelid irritation, possibly related to Ilast wipes.