CHAPTER 3

Results

3.1 Patients Characteristics

A total of 66 patients were screened and 50 patients with eligibility were recruited into the study. All subjects were randomized into two groups; shallot group (25 subjects) and placebo group (25 subjects). Each subject in both groups received cetirizine 10 mg once daily. Subjects in the shallot group received oral capsules of 3 grams shallot (equivalent to 1½ bulbs of fresh shallot) daily for 4 weeks and subjects in the placebo group received similar amount of placebo capsules in combination with cetirizine. At the end of the study, there were 47 subjects who completed the study. Two subjects lost follow-up during the study. One subject was terminated from the study due to the use of other antihistamines and decongestant. However, 15 subjects in both groups were excluded from final analysis due to poor compliance less than 85%. Finally, 18 subjects in the shallot group and 14 subjects in the placebo group were included into final analysis (Figure 3.1). The characteristics data of all subjects included sex, age, duration of allergic rhinitis (AR) symptoms, weight, height, blood pressure, and pulse rates were similar between two groups. There was no statistical differences between groups. The number of patients who associated ocular symptoms were 18 in the shallot group and 13 in the placebo group. No statistical difference of associated ocular symptoms between groups was observed (Table 3.1). The baseline data comprised subjective, objective parameters, and laboratory investigation were similar in both groups. Subjective data included total nasal symptom score (TNSS), total ocular symptoms score (TOSS), individual of nasal and ocular symptoms score, visual analog score of overall symptoms (VAS), quality of life (QOL), and subject satisfaction. Objective data included nasal airway resistance (NAR) and nasal cytology. There was no statistical difference of all data between groups (Table 3.2).

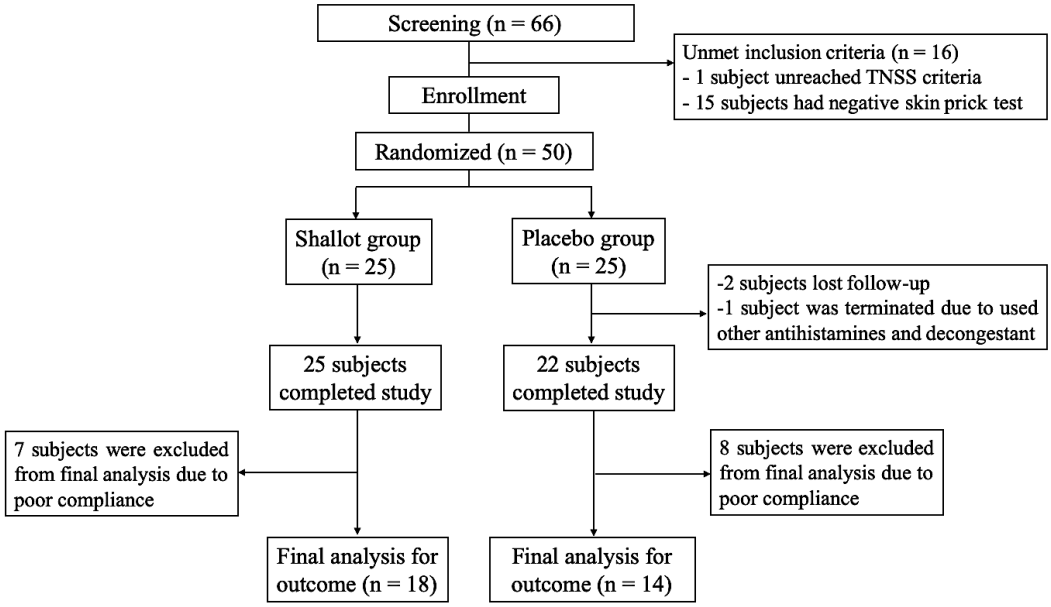

Figure 3.1 Flow chart of patients during the study

Table 3.1 Demographic data

Characteristics	**Shallot** **n = 18**	**Placebo** **n =14**	***p*-value**
Sex, n (%) • Male • Female	 6 (33.33) 12 (66.67)	 5 (35.71) 9 (64.29)	 0.888
Associated ocular symptoms, n	18	13	0.249
Age, years	41.1 ± 11.7	35.2 ± 12.3	0.238
Duration of AR symptoms, years	10.3 ± 6.9	12.3 ± 7.5	0.303
Weight, kg	65.9 ± 19.8	62.8 ± 15.6	0.879
Height, m	1.6 ± 0.1	1.6 ± 0.1	0.411
Body mass index (BMI), kg/m^2	24.3 ± 5.6	23.6 ± 4.4	1.000
Systolic blood pressure, mmHg	115.1 ± 12.2	111.6 ± 9.8	0.332
Diastolic blood pressure, mmHg	71.8 ± 8.6	67.2 ± 9.5	0.159
Pulse rate, beats/min	75.8 ± 9.6	78.4 ± 12.9	0.253

Values were demonstrated in mean ± SD

Statistical analysis: Wilcoxon's rank sum test

Table 3.2 Baseline data of all subjects in the study

Baseline data	Shallot (n = 18)	Placebo (n =14)	*p*-value
Total nasal symptom score (TNSS)	7.2 ± 1.2	7.2 ± 1.2	0.937
Itchy nose	1.7 ± 0.5	1.7 ± 0.6	0.873
Nasal obstruction	1.7 ± 0.5	1.9 ± 0.4	0.224
Sneezing	1.9 ± 0.5	1.8 ± 0.7	0.540
Rhinorrhea	1.9 ±0.7	2.1 ± 0.7	0.464
Total ocular symptom score (TOSS)	2.8 ± 2.1	2.6 ± 1.3	0.923
Itchy eyes	1.4 ± 0.7	1.4 ± 0.5	0.899
Watery eyes	0.7 ± 0.7	1.2 ± 1.0	0.181
Eye redness	0.6 ± 0.7	0.5 ± 0.6	0.946
Visual analog score (VAS) of overall symptoms	5.8 ± 1.7	5.4 ± 2.2	0.758
Quality of life			
Rhinitis symptoms (RS)	11.6 ± 2.2	11.6 ± 2.8	0.743
Eyes symptoms (ES)	9.5 ± 2.7	8.4 ± 2.8	0.339
Other symptoms (OS)	20.7 ± 6.1	20.4 ± 6.9	0.648
Physical functioning (PF)	5.2 ± 1.8	5.8 ± 2.6	0.602
Role limitation (RL)	5.3 ± 1.9	6.0 ± 2.5	0.602
Sleep	6.9 ± 2.6	6.0 ± 2.9	0.282
Social functioning (SF)	5.8 ± 2.7	6.1 ± 3.1	0.922
Emotions (E)	10.3 ± 5.0	13.3 ± 4.9	0.062
Overall health (OH)	3.0 ± 0.6	2.9 ± 0.8	0.580
Absenteeism	0.3 ± 1.0	0.2 ± 0.6	0.817
NAR, Pa/cm^3/s	0.3 ± 0.2	0.2 ± 0.1	0.109
Nasal cytology, n			
Neutrophil	0.4 ± 1.2	1.7 ± 3.2	0.055
Eosinophil	0.6 ± 1.3	2.1 ± 2.9	0.101
Basophil	0.1 ± 0.2	0.1 ± 0.4	0.408

Table 3.2 Baseline data of all subjects in the study (continued)

Baseline data	Shallot (n = 18)	Placebo (n =14)	*p*-value
Nasal cytology, n			
Lymphocyte	0 ± 0	0 ± 0	1.000
Macrophage	0 ± 0	0 ± 0	1.000
Laboratory			
Hemoglobin, g/dL	13.0 ± 1.0	13.0 ± 1.4	0.894
Hematocrit, %	39.4 ± 3.0	39.4 ± 4.0	0.864
Platelets, $x10^3/\mu L$	285.7 ± 79.6	288.7 ± 81.0	0.805
White blood cell, $x10^3/\mu L$	6.8 ± 1.6	6.6 ± 2.9	0.305
Neutrophil, %	53.7 ± 9.4	56.1 ± 10.9	0.518
Lymphocyte, %	36.7 ± 10.0	32.9 ± 8.1	0.296
Monocyte, %	5.9 ± 1.6	5.9 ± 1.7	0.985
Eosinophil, %	3.3 ± 1.7	4.6 ± 3.3	0.335
Basophil, %	0.4 ± 0.5	0.6 ± 0.6	0.387
Blood urea nitrogen (BUN), mg/dL	12.9 ± 4.5	12.1 ± 3.5	0.606
Creatinine (Cr), mg/dL	0.8 ± 0.1	0.8 ± 0.2	0.352
eGFR (ml/min)	95.6 ± 13.6	103.2 ± 14.2	0.149
Aspartate aminotransferase level (AST), U/L	18.8 ± 5.3	18.6 ± 5.7	0.804
Alanine aminotransferase level (ALT), U/L	21.1 ± 14.4	19.1 ± 14.3	0.392

Values were demonstrated in mean ± SD

Statistical analysis: Wilcoxon's rank sum test

3.2 Skin prick test

The allergens that subjects in this study had positive test were house dust mite *D. farina*, house mite *D. pteronyssinus*, American cockroach, careless weed, para grass, and cat hair (Table 3.3).

Table 3.3 Number of patients with positive skin prick test

Allergens	Shallot (n = 18)	Placebo (n = 14)
House mite *D. farina*	14	13
House mite *D. pteronyssinus*	14	13
American cockroach	10	7
Careless weed	2	0
Para grass	2	0
Cat hair	0	2

3.3 Subjective assessments

3.3.1 Total nasal symptom score (TNSS) and nasal symptoms

For TNSS, subjects in both groups showed significant improvement after 2 weeks of treatment. In the shallot group, mean TNSS was reduced from 7.2 ± 1.2 to 3.0 ± 1.8 after 4 weeks of treatment. Likewise, mean TNSS was reduced from 7.2 ± 1.2 to 3.3 ± 2.8 after 4 weeks of treatment in the placebo group, shown in Table 3.4 and Figure 3.2. However, there was no statistical difference between groups, shown in Table 3.5.

Sub analysis of nasal symptoms, itchy nose in the shallot group was significantly reduced after 2 weeks of treatment whereas it was significantly reduced after 3 weeks of treatment in the placebo group, shown in Table 3.4 and Figure 3.3. Sneezing that was showed in Table 3.4 and Figure 3.5, in the shallot group was significantly improved after treatment after 2 weeks of treatment but it was significantly improved after 4 weeks of treatment in placebo group. In addition, rhinorrhea was significantly reduced after 2 weeks of treatment in the shallot group and after 1 week of treatment in the placebo group (Table 3.4 and Figure 3.6). And the nasal obstruction, there was significantly reduced after 2 weeks of treatment in both groups (Table 3.4 and Figure 3.4). However, all of nasal symptoms were no statistical difference between groups, shown in Table 3.5.

The responders with more than 50% of improvement after treatment was classified as “50% responder rate”. The 50% responder rate after 4 weeks of treatment for itchy

nose in the shallot group was slightly higher than the placebo group without statistically significant between groups (Figure 3.7). For nasal obstruction, sneezing, and rhinorrhea, the 50% responder rate after 4 weeks of treatment in the shallot group were higher than the placebo group without statistically significant between groups (Figure 3.8, Figure 3.9 and Figure 3.10).

Table 3.4 TNSS and nasal symptoms at week 0, 1, 2, 3, and 4 in both groups

	Shallot					**Placebo**				
	Week 0	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 0**	**Week 1**	**Week 2**	**Week 3**	**Week 4**
TNSS	7.2 ± 1.2	5.0 ± 1.7	3.8 ± 1.8	3.4 ± 2.5	3.0 ± 1.8	7.2 ± 1.2	4.4 ± 2.6	4.2 ± 2.8	3.9 ± 2.9	3.3 ± 2.8
p-value	-	0.114	< 0.001*	< 0.001*	< 0.001*	-	0.270	0.015*	0.010*	< 0.001*
Itchy nose	1.7 ± 0.5	1.2 ± 0.6	0.9 ± 0.7	0.8 ± 0.8	0.7 ± 0.5	1.7 ± 0.6	1.1 ± 0.8	1.0 ± 0.9	0.8 ± 0.8	0.7 ± 0.7
p-value	-	0.731	0.002*	0.003*	< 0.001*	-	0.365	0.168	0.019*	< 0.001*
Nasal obstruction	1.7 ± 0.5	1.5 ± 0.5	1.1 ± 0.5	1.1 ± 0.7	1.0 ± 0.6	1.9 ± 0.4	1.3 ± 0.8	1.2 ± 0.8	1.1 ± 0.8	0.9 ± 0.9
p-value	-	1.000	0.049*	0.011*	0.006*	-	1.000	0.121	0.019*	0.003*
Sneezing	1.9 ± 0.5	1.0 ± 0.7	0.8 ± 0.8	0.7 ± 0.6	0.5 ± 0.5	1.8 ± 0.7	1.0 ± 0.5	0.9 ± 0.6	0.8 ± 0.7	0.7 ±0.7
p-value	-	0.114	0.003*	< 0.001*	< 0.001*	-	1.000	0.365	0.198	0.004*
Rhinorrhea	1.9 ± 0.7	1.3 ± 0.6	1.0 ± 0.7	0.8 ± 0.8	0.9 ± 0.8	2.1 ± 0.7	1.0 ± 0.9	1.1 ± 0.8	1.1 ± 0.8	1.0 ± 0.8
p-value	-	0.731	0.016*	< 0.001*	< 0.001*	-	0.013*	0.004*	0.034*	< 0.001*

Values were demonstrated in mean ± SD, *compared with week 0, statistical analysis: Friedman test

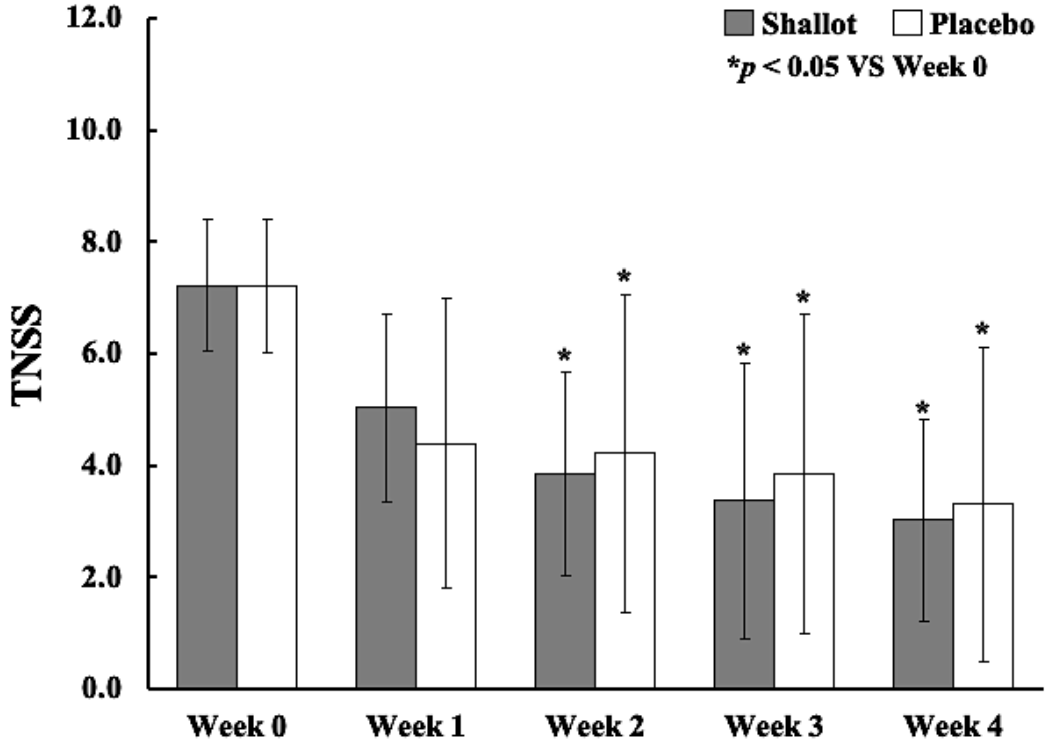

Figure 3.2 TNSS at week 0, 1, 2, 3, and 4 in both groups

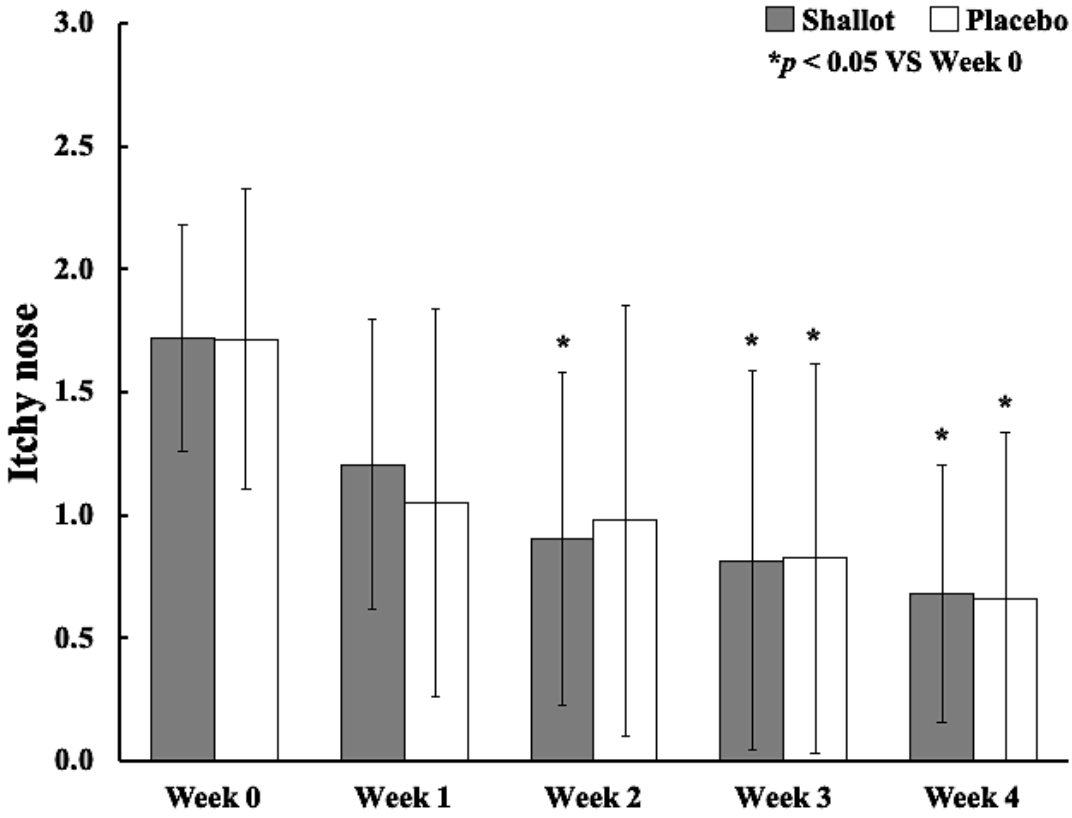

Figure 3.3 Itchy nose at week 0, 1, 2, 3, and 4 in both groups

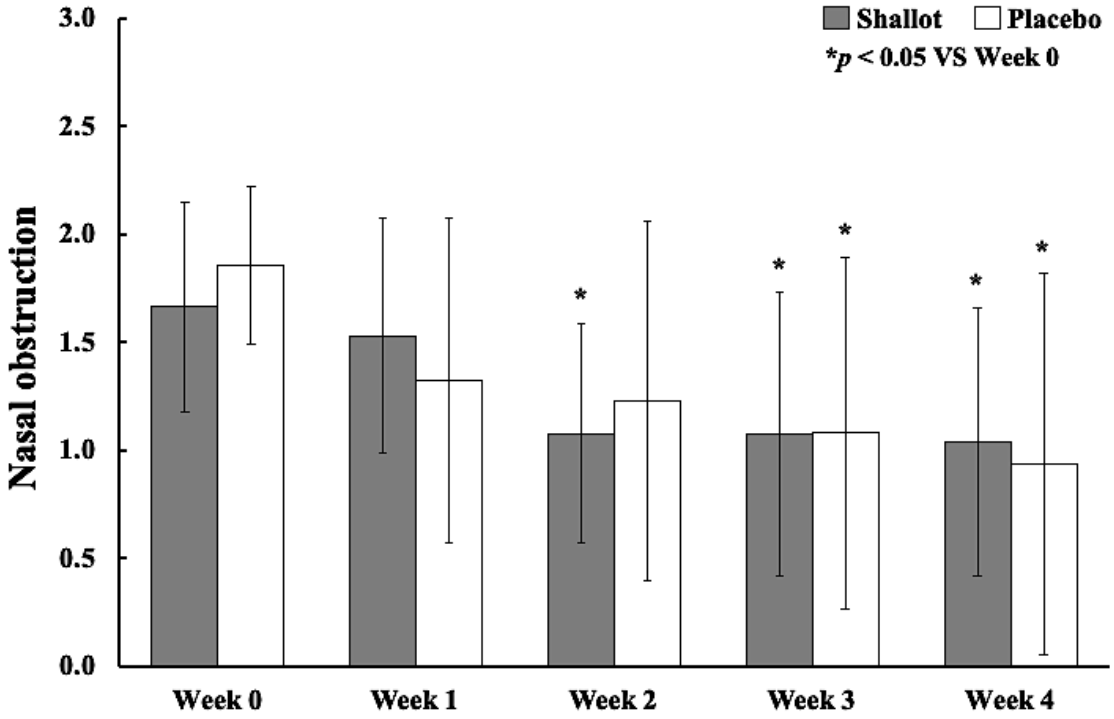

Figure 3.4 Nasal obstruction at week 0, 1, 2, 3, and 4 in both groups

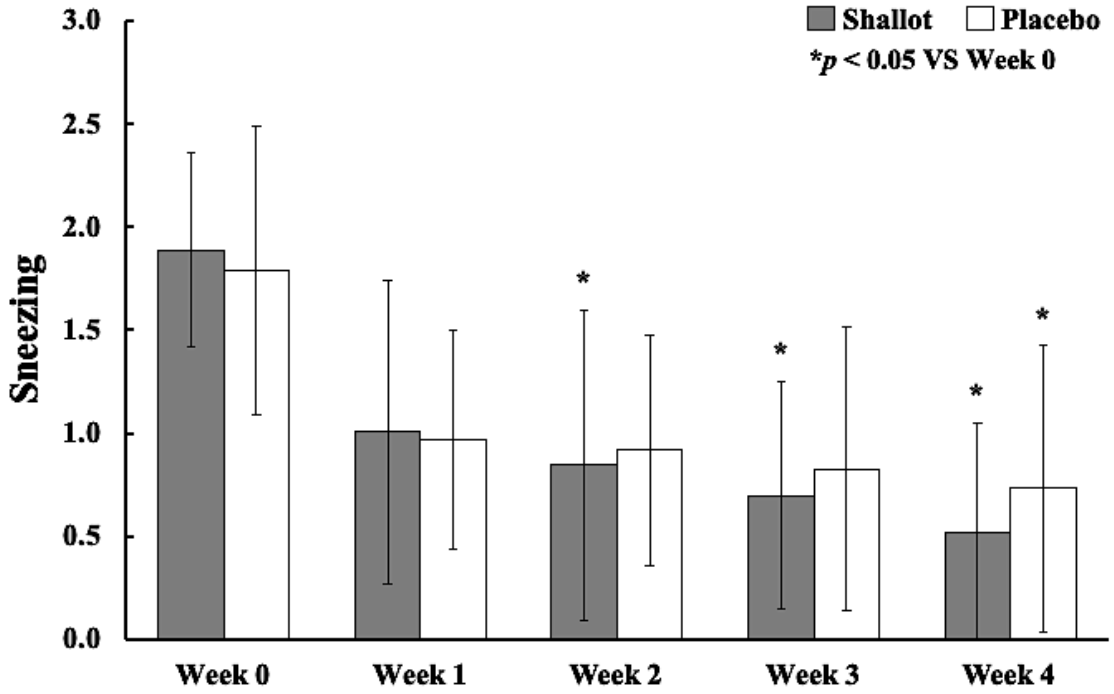

Figure 3.5 Sneezing at week 0, 1, 2, 3, and 4 in both groups

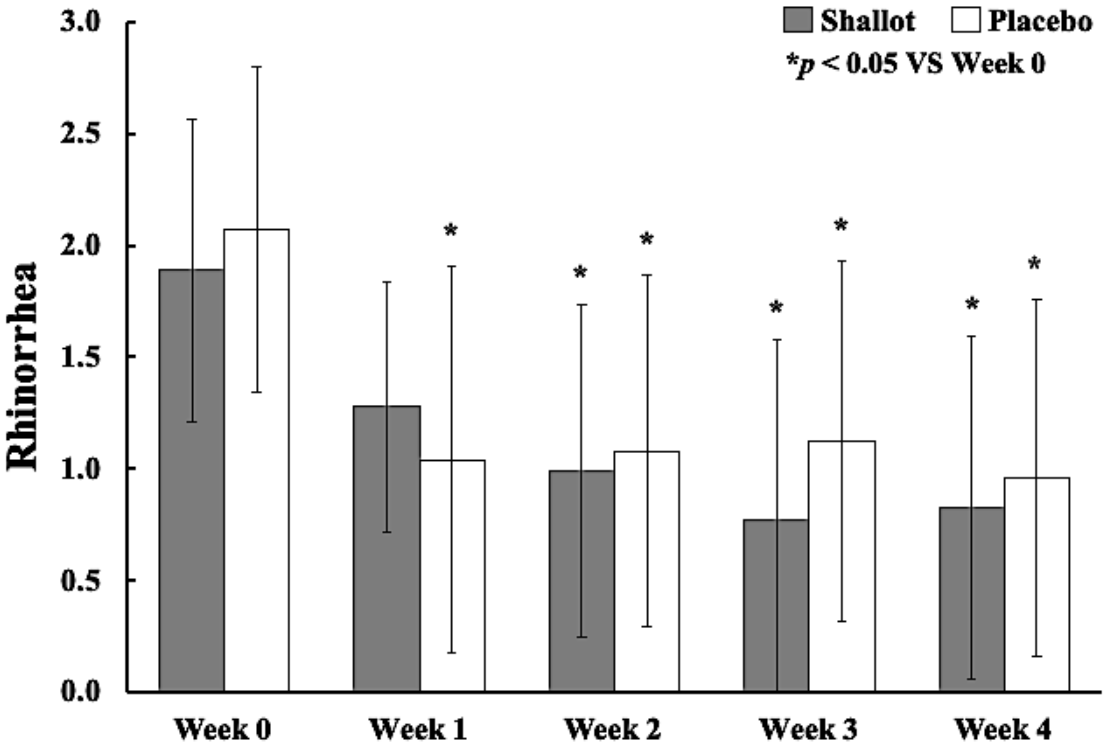

Figure 3.6 Rhinorrhea at week 0, 1, 2, 3, and 4 in both groups

Table 3.5 Percent mean changes from week 0 in TNSS and nasal symptoms at week 1, 2, 3, and 4 in both groups

Groups	% mean changes from week 0			
	Week 1	Week 2	Week 3	Week 4
TNSS				
Shallot	-30.5	-46.9	-53.6	-58.4
Placebo	-39.3	-41.7	-46.7	-54.4
***p*-value**	0.322	0.834	0.746	0.790
Itchy nose				
Shallot	-30.5	-48.2	-53.3	-61.2
Placebo	-39.0	-43.3	-52.3	-61.9
***p*-value**	0.389	0.878	0.985	0.893
Nasal obstruction				
Shallot	-8.0	-34.7	-34.7	-36.9
Placebo	-28.0	-33.1	-40.9	-48.5
***p*-value**	0.147	0.970	0.732	0.493

Table 3.5 Percent mean changes from week 0 in TNSS and nasal symptoms at week 1, 2, 3, and 4 in both groups (continued)

Groups	% mean changes from week 0			
	Week 1	**Week 2**	**Week 3**	**Week 4**
Sneezing				
Shallot	-46.4	-54.9	-62.7	-72.4
Placebo	-45.4	-48.3	-53.3	-58.4
***p*-value**	0.985	0.661	0.675	0.493
Rhinorrhea				
Shallot	-32.3	-47.3	-58.9	-56.1
Placebo	-49.1	-47.2	-45.2	-53.1
***p*-value**	0.382	0.849	0.341	0.568

Statistical analysis: Wilcoxon's rank sum test

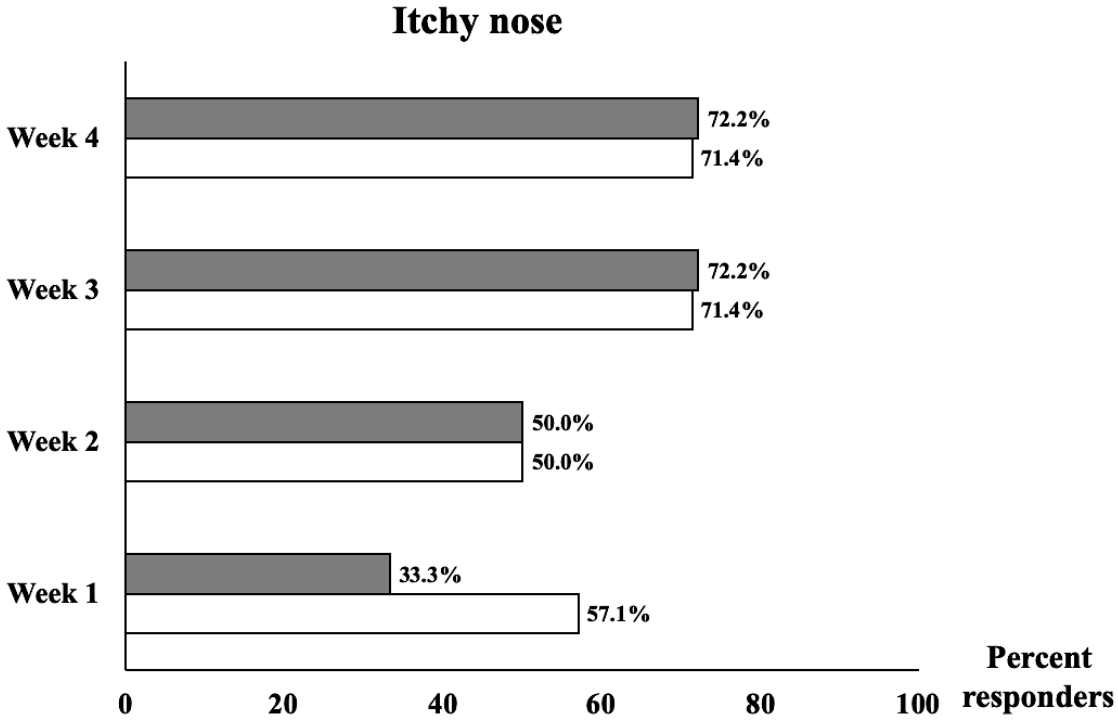

Figure 3.7 50% responder rate of itchy nose after treatment

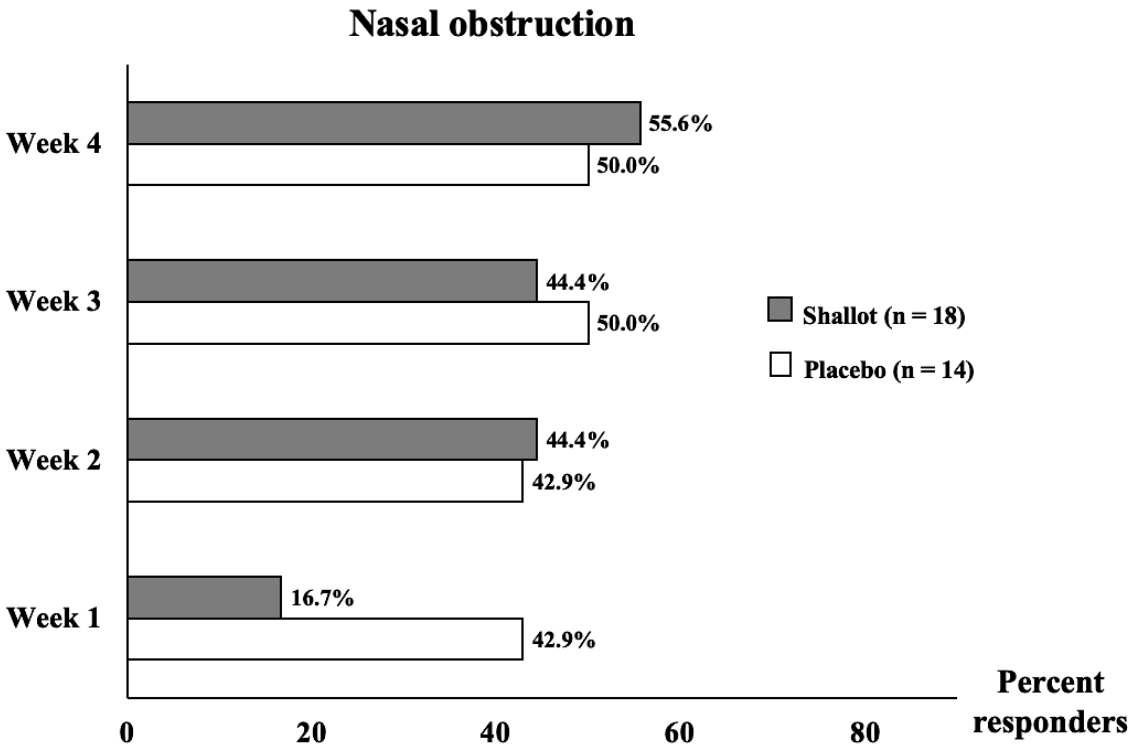

Figure 3.8 50% responder rate of nasal obstruction after treatment

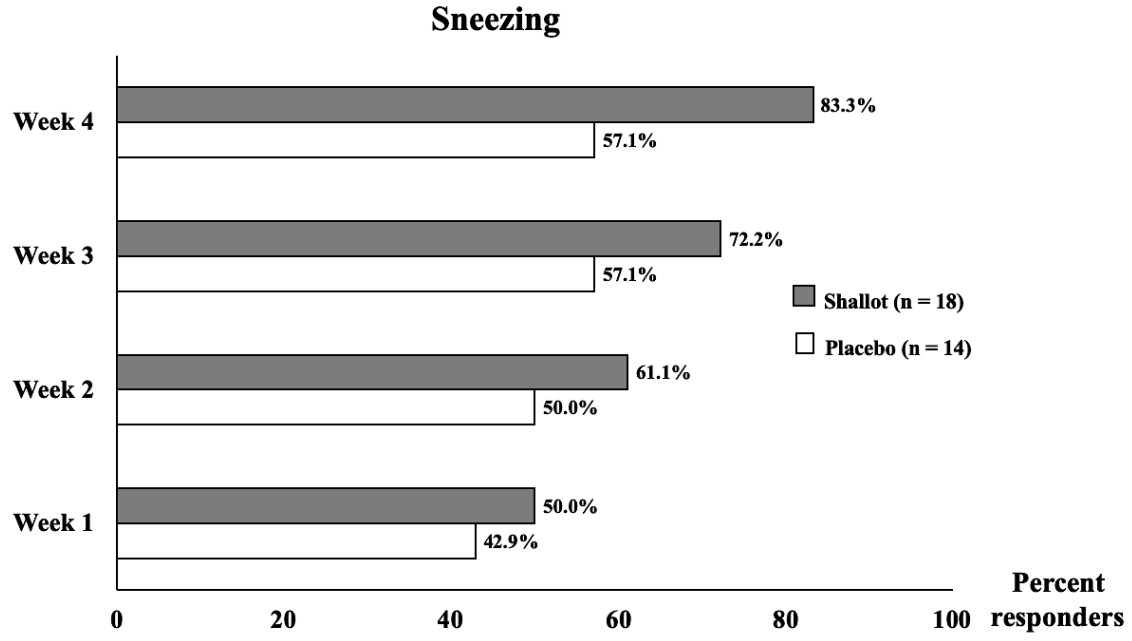

Figure 3.9 50% responder rate of sneezing after treatment

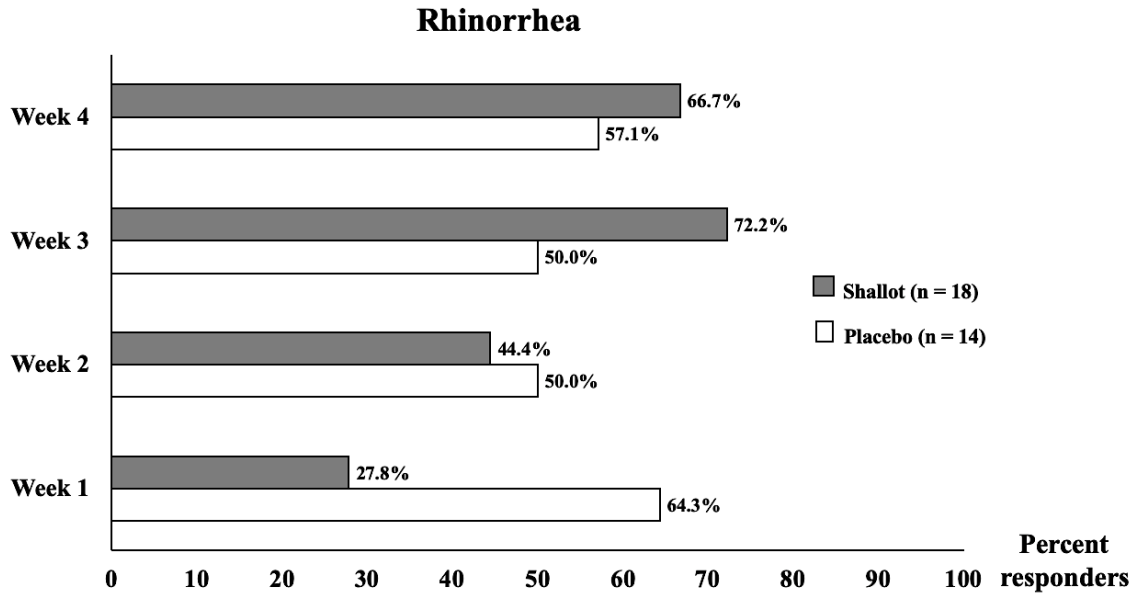

Figure 3.10 50% responder rate of rhinorrhea after treatment

3.3.2 Total ocular symptom score (TOSS) and ocular symptoms

Total ocular symptom score included itchy eyes, watery eyes, and eye redness. Comparing to week 0 (baseline), subjects in both groups showed significantly improved TOSS after 2 weeks of treatment (Table 3.6 and Figure 3.11). In the shallot group, mean TOSS was reduced from 2.8 ± 2.1 to 0.9 ± 0.9 after 4 weeks of treatment. Likewise, mean TOSS was reduced from 2.6 ± 1.3 to 0.9 ± 1.6 after 4 weeks of treatment in the placebo group. However, there was no statistical difference between groups, shown in Table 3.7.

Sub analysis of ocular symptoms, itchy eyes was only significantly improved after 2 weeks of treatment in the shallot group whereas it was no changed in the placebo group, shown in Table 3.6 and Figure 3.12. In addition, watery eyes was only significantly improved after 4 weeks of treatments in the placebo group, shown in Table 3.6 and Figure 3.13. However, there was no change in eyes redness after treatment in both groups, shown in Table 3.6 and Figure 3.14. Alternatively, there were no statistically significant on itchy eyes, watery eyes, and eye redness between groups after treatment (Table 3.7).

After 4 weeks of treatment, the 50% responder rate for itchy eyes and watery eyes in the placebo group was higher than the shallot group without statistically significant between group (Figure 3.15 and Figure 3.17). In contrast, the 50% responder rate for eye redness in the shallot group was higher than in the placebo group without statistically significant between group after 4 weeks of treatment (Figure 3.16).

Table 3.6 TOSS and ocular symptoms at week 0, 1, 2, 3, and 4 in both groups

	Shallot					**Placebo**				
	Week 0	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 0**	**Week 1**	**Week 2**	**Week 3**	**Week 4**
TOSS	2.8 ± 2.1	1.5 ± 1.3	1.1 ± 1.3	1.0 ± 1.2	0.9 ± 0.9	2.6 ± 1.3	1.5 ± 1.8	1.1 ± 1.6	0.8 ± 1.6	0.9 ± 1.6
p-value	-	0.917	0.002*	0.011*	0.013*	-	1.000	0.002*	0.001*	0.001*
Itchy eyes	1.3 ± 0.8	0.7 ± 0.6	0.5 ± 0.5	0.4 ± 0.5	0.4 ± 0.5	1.4 ± 0.5	0.8 ± 0.9	0.6 ± 0.8	0.4 ± 0.7	0.5 ± 0.8
p-value	-	0.512	0.007*	0.006*	0.019*	-	1.000	0.558	0.051	0.121
Watery eyes	0.7 ± 0.8	0.6 ± 0.6	0.4 ± 0.6	0.4 ± 0.6	0.4 ± 0.5	1.1 ± 1.0	0.6 ± 0.8	0.3 ± 0.6	0.3 ± 0.6	0.2 ± 0.7
p-value	-	0.433	0.433	0.433	0.433	-	1.000	0.086	0.086	0.015*
Eye redness	0.5 ± 0.8	0.2 ± 0.5	0.3 ± 0.4	0.2 ± 0.3	0.1 ± 0.2	0.4 ± 0.6	0.2 ± 0.4	0.1 ±0.3	0.2 ± 0.4	0.2 ± 0.4
p-value	-	0.569	0.569	0.569	0.569	-	0.203	0.203	0.203	0.203

Values were demonstrated in mean ± SD, *compared with week 0, statistical analysis: Friedman test

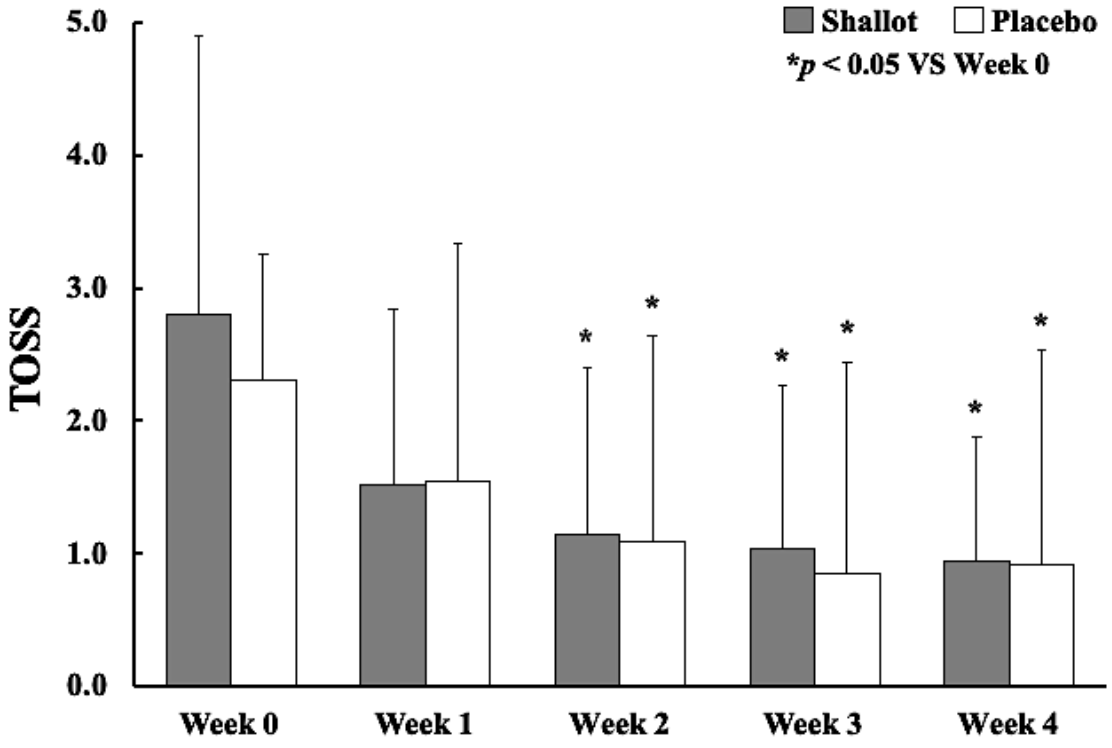

Figure 3.11 TOSS at week 0, 1, 2, 3, and 4 in both groups

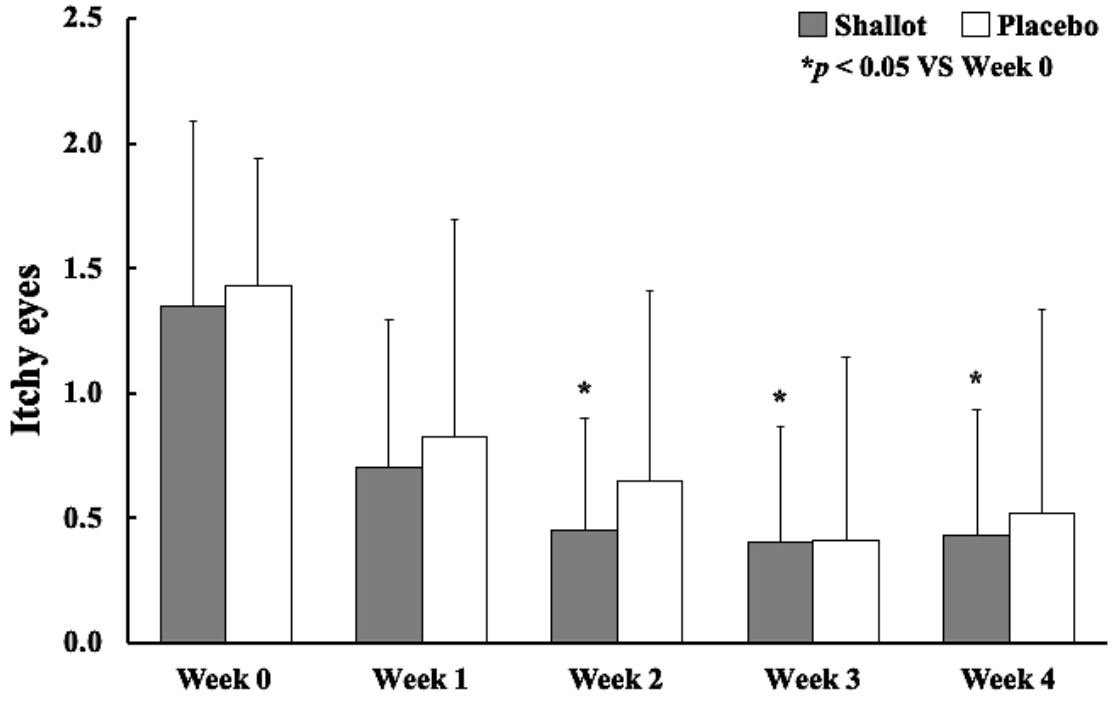

Figure 3.12 Itchy eyes at week 0, 1, 2, 3, and 4 in both groups

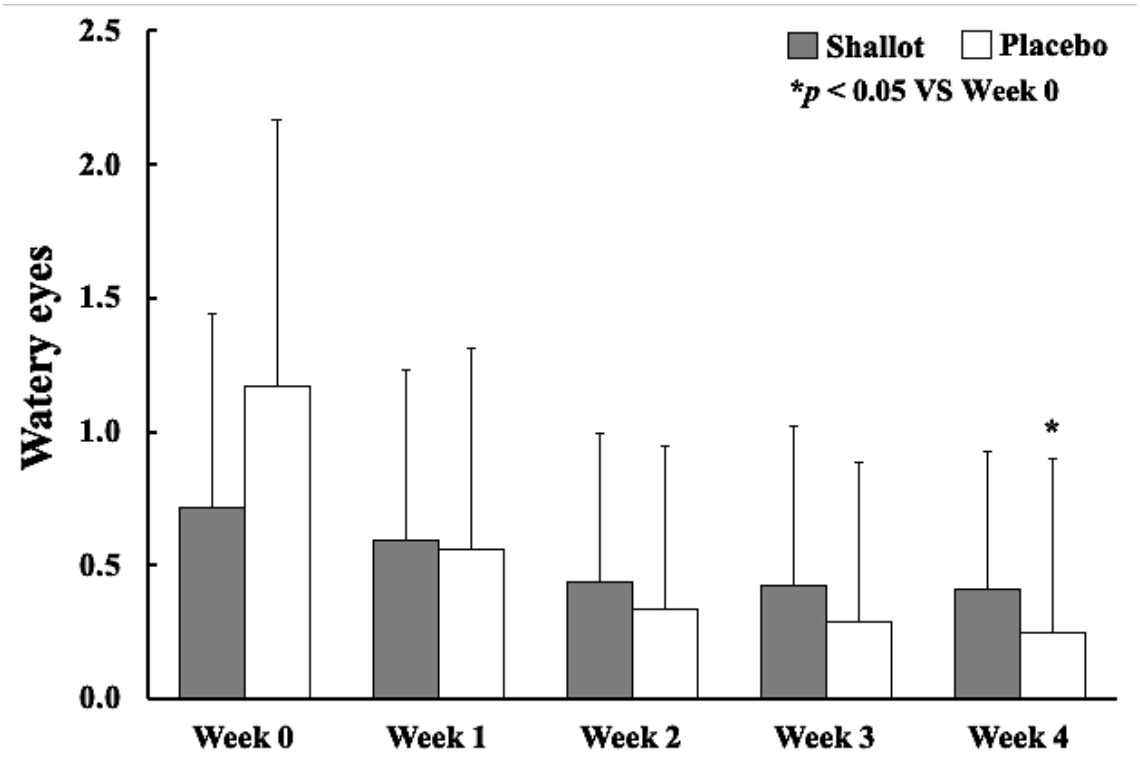

Figure 3.13 Watery eyes at week 0, 1, 2, 3, and 4 in both groups

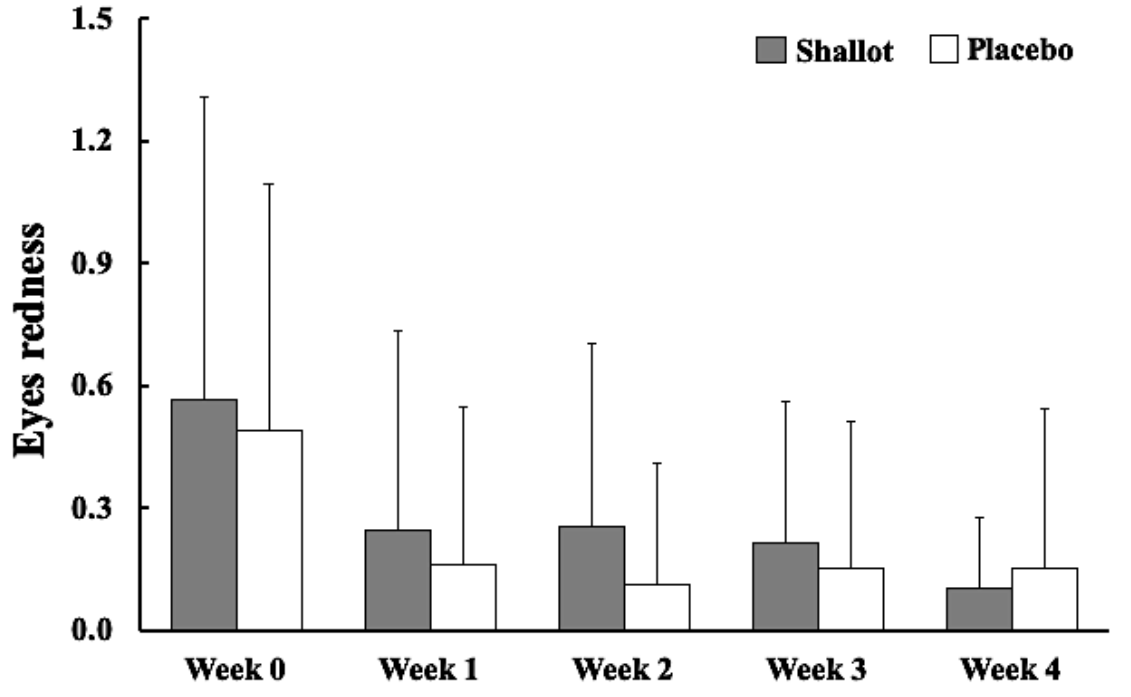

Figure 3.14 Eye redness at week 0, 1, 2, 3, and 4 in both groups

Table 3.7 Percent mean changes from week 0 in TOSS and ocular symptoms at week 1, 2, 3, and 4 in both groups

Groups	% mean changes from week 0			
	Week 1	**Week 2**	**Week 3**	**Week 4**
TOSS				
Shallot	-45.1	-58.5	-62.1	-65.5
Placebo	-39.3	-57.0	-66.4	-63.8
***p*-value**	0.732	0.790	0.648	0.819
Itchy eyes				
Shallot	-45.0	-63.1	-66.3	-64.7
Placebo	-43.1	-55.7	-73.0	-64.9
***p*-value**	0.924	0.789	0.673	0.924
Watery eyes				
Shallot	-10.3	-32.9	-35.2	-36.3
Placebo	-48.6	-67.2	-71.5	-74.8
***p*-value**	0.249	0.190	0.224	0.111
Eye redness				
Shallot	-42.3	41.0	-47.7	-66.3
Placebo	-53.1	-63.3	-55.1	-55.1
***p*-value**	0.966	0.694	1.000	0.867

Statistical analysis: Wilcoxon's rank sum test

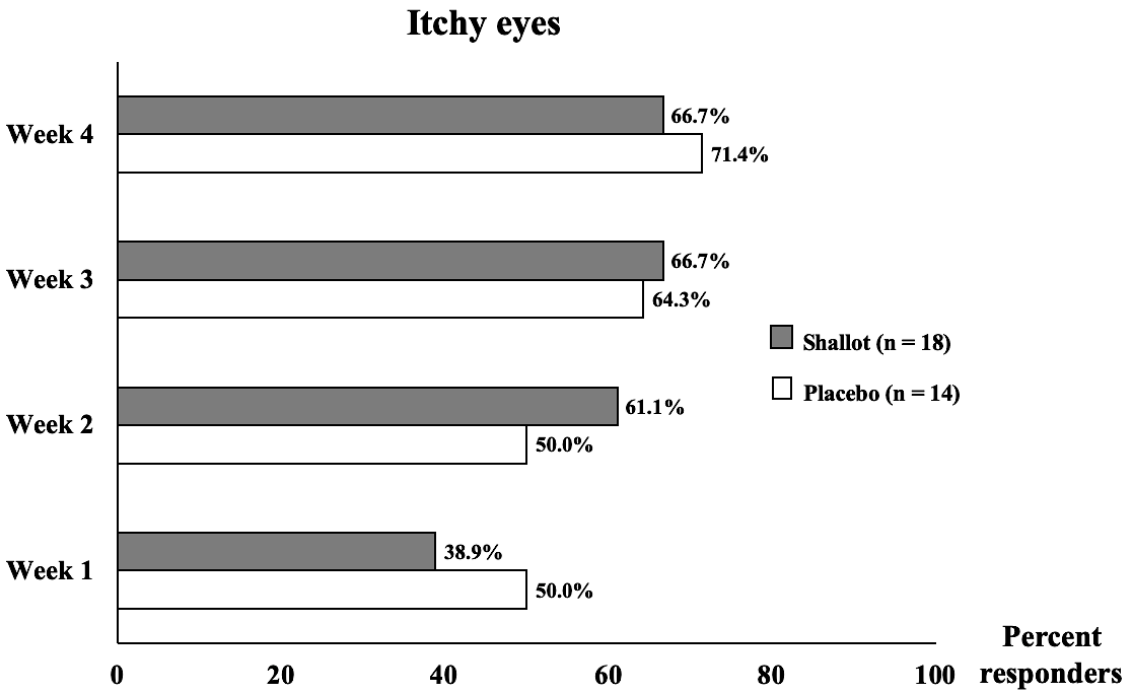

Figure 3.15 50% responder rate of itchy eyes after treatment

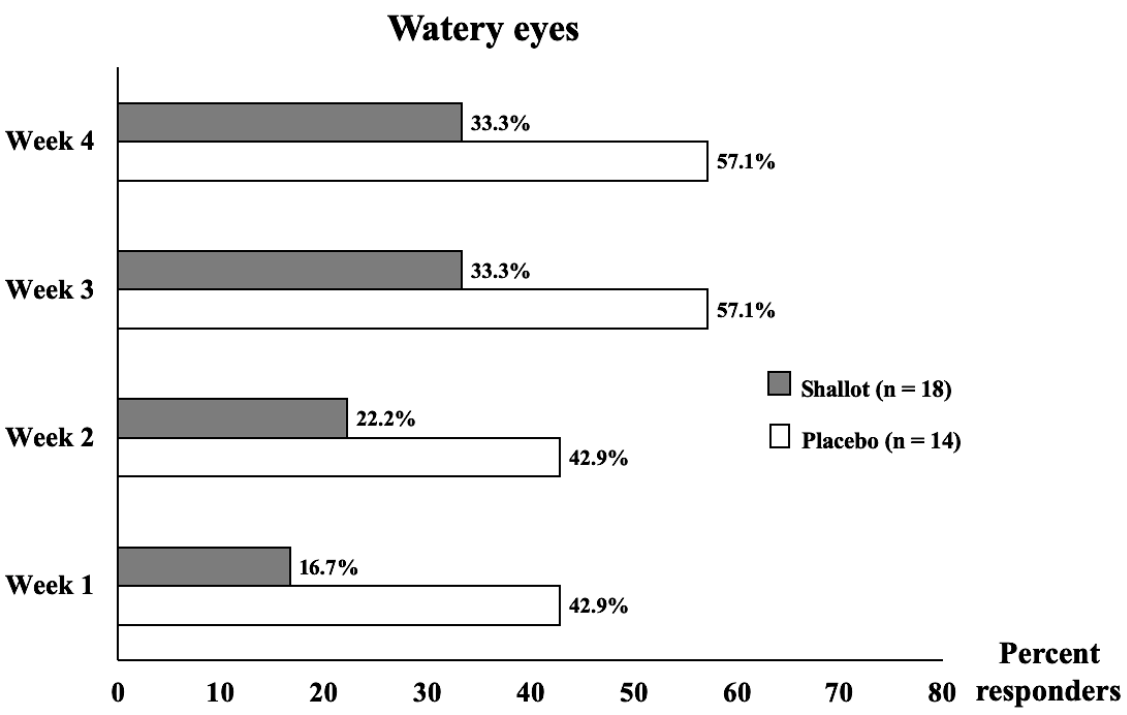

Figure 3.16 50% responder rate of watery eyes after treatment

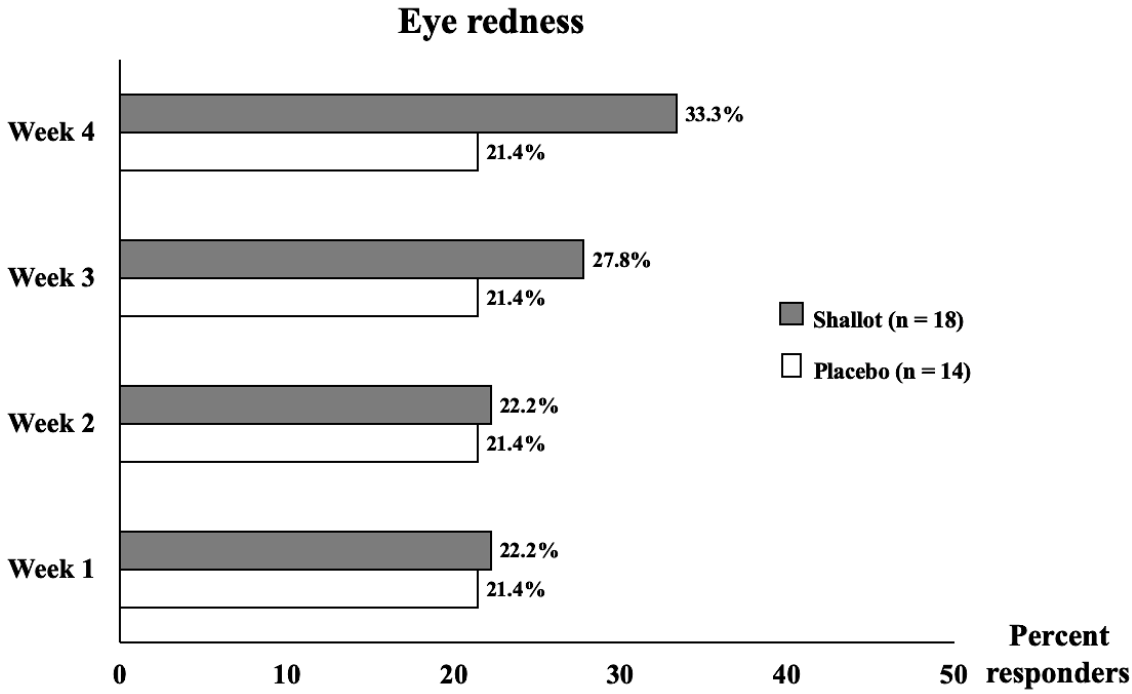

Figure 3.17 50% responder rate of eye redness after treatment

3.3.3 Visual analog score (VAS) of overall symptoms

Subjects in both groups showed significantly decreased of VAS after 4 weeks of treatment. Mean VAS in the shallot group was reduced from 5.8 ± 1.7 to 3.0 ± 2.1. Similarly, Mean VAS was reduced from 5.4 ± 2.2 to 3.1 ± 2.5 in the shallot group, shown in Table 3.8 and Figure 3.18. However, the percent mean changes in VAS was no statistical difference between groups, shown in Table 3.9.

After receiving the treatment for 2 weeks, 3 patients (16.7%) in the shallot group and 2 patients (14.3%) in the placebo group showed favorable improvement of VAS (reduction of post-treatment scores by 50%). Moreover, after 4 weeks of treatment, 9 patients (50.0%) in the shallot group and 6 patients (42.9%) in the placebo showed favorable improvement of VAS with no statistically significant that shown in Table 3.10 and Figure 3.19.

Table 3.8 Mean VAS at week 0, 2, and 4 in both groups

	Shallot			Placebo		
	Week 0	**Week 2**	**Week 4**	**Week 0**	**Week 2**	**Week 4**
VAS	5.8 ± 1.7	4.1 ± 1.4	3.0 ± 2.1	5.4 ± 2.2	4.0 ± 2.2	3.1 ± 2.5
***p*-value**	-	0.470	< 0.001*	-	0.142	0.002*

Values were demonstrated in mean ± SD, *compared with week 0

Statistical analysis: Friedman test

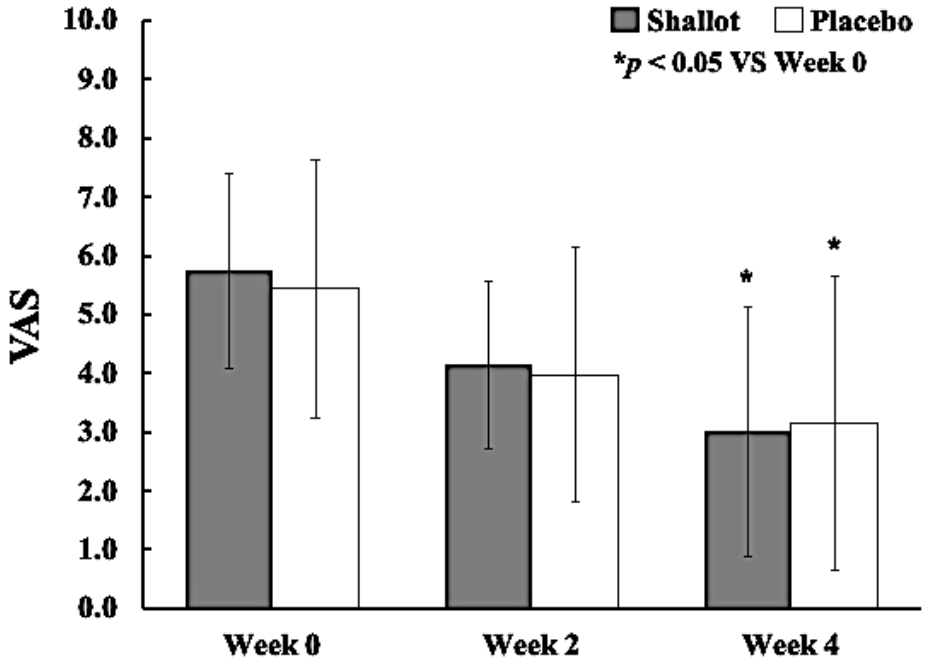

Figure 3.18 VAS at week 0, 2, 4 in both groups

Table 3.9 Percent mean changes from week 0 in VAS at week 2 and 4 in both groups

Groups	**% mean changes from week 0 in VAS**	
	Week 2	**Week 4**
Shallot	-27.9	-47.3
Placebo	-27.0	-42.5
***p*-value**	0.924	0.761

Statistical analysis: Wilcoxon's rank sum test

Table 3.10 The number of 50% responder rate of VAS improvement after treatment for 2 and 4 weeks

Groups	Number of 50% VAS responder rate of VAS improvement (%)	
	Week 2	Week 4
Shallot (n = 18)	3 (16.7)	9 (50.0)
Placebo (n = 14)	2 (14.3)	6 (42.9)

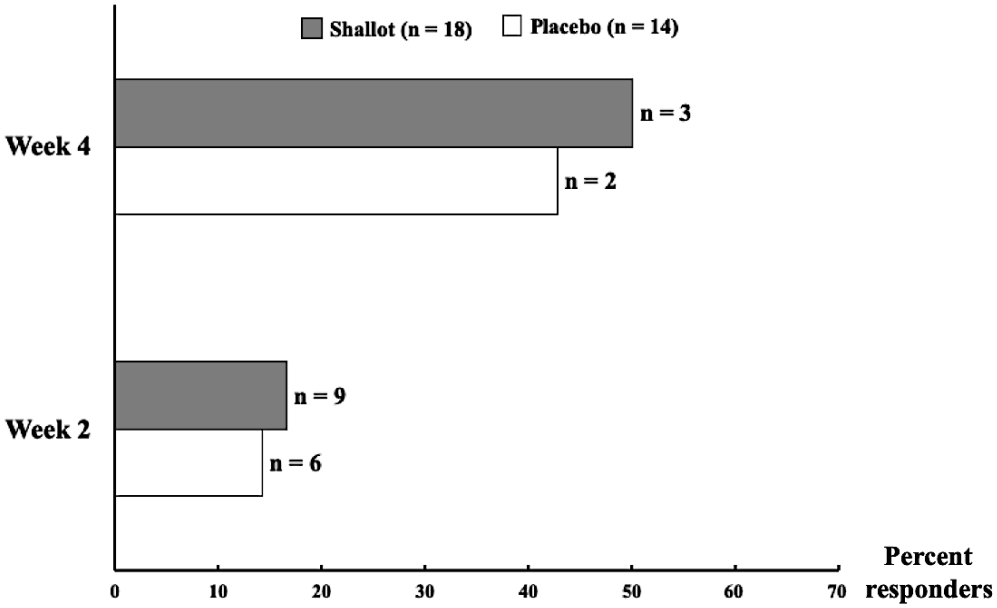

Figure 3.19 50% responder rate of VAS improvement after treatment for 2 and 4 weeks

3.3.4 Subject satisfaction

The subjects' satisfactory score (%) after receiving the treatment were 77.6 ± 14.7 in the shallot group and 83.9 ± 12.7 in the placebo group. There was no statistical difference between groups after 4 weeks of treatment (Table 3.11).

Table 3.11 Mean of subjects' satisfactory score (%) after treatment for 4 weeks in both groups

	Shallot	Placebo	*p*-value
Subject satisfaction (%)	77.6 ± 14.7	83.9 ± 12.7	0.174

3.3.5 Quality of life

For the quality of life, subjects in both groups showed significantly reduced the score from Rhinoconjunctivitis Quality of life questionnaire (Rcq-36) in almost every dimension excepted the role limitation (RL) and absenteeism after treatment for 4 weeks (Table 3.12). However, there was no statistical difference between groups in almost every dimensions and independent items. In the dimension of emotions, there was significant difference between groups (Table 3.13).

Table 3.12 Mean score of Rhinoconjunctivitis Quality of life questionnaire (Rcq-36) at week 0 and 4 in both groups

Dimensions and independent items	Shallot		*p*-value	Placebo		*p*-value
	Week 0	Week 4		Week 0	Week 4	
Symptoms						
Rhinitis symptoms (RS)	11.6 ± 2.2	8.4 ± 1.9	< 0.001*	11.6 ± 2.8	7.9 ± 2.2	0.003*
Eye symptoms (ES)	9.5 ± 2.7	6.2 ± 1.6	0.001*	8.4 ± 2.8	5.9 ± 2.6	0.020*
Other symptoms (OS)	20.7 ± 6.1	13.5 ± 4.7	0.001*	20.4 ± 6.9	13.7 ± 5.7	0.001*
Physical functioning (PF)	5.2 ± 1.8	3.6 ± 1.2	0.003*	5.8 ± 2.6	3.9 ± 1.7	0.003*
Role limitation (RL)	5.3 ± 1.9	4.7 ± 2.4	0.252	6.0 ± 2.5	4.5 ± 2.2	0.051
Sleep	6.9 ± 2.6	4.6 ± 1.8	0.003*	6.0 ± 2.9	4.1 ± 1.7	0.006*
Social functioning (SF)	5.8 ± 2.7	4.2 ± 1.9	0.017*	6.1 ± 3.1	4.1 ± 2.2	0.010*
Emotions (E)	10.3 ± 5.0	7.3 ± 3.6	0.001*	13.3 ± 4.9	7.8 ± 4.1	0.001*
Overall health (OH)	3.0 ± 0.6	2.4 ± 0.6	0.005*	2.9 ± 0.8	2.3 ± 0.6	0.024*
Absenteeism	0.3 ± 1.0	0 ± 0	0.180	0.2 ± 0.6	0.1 ± 0.5	0.317

Values were demonstrated in mean ± SD, *compared with week 0

Statistical analysis: Wilcoxon's signed rank test

Table 3.13 Mean changes from week 0 in scores of the Rhinoconjunctivitis Quality of life questionnaire (Rcq-36) in both groups

Dimensions and independent items	Shallot	Placebo	*p*-value
Symptoms			
Rhinitis symptoms (RS)	-3.2 ± 2.4	-3.8 ± 2.7	0.466
Eye symptoms (ES)	-3.3 ± 3.0	-2.5 ± 3.2	0.552
Other symptoms (OS)	-7.2 ± 5.8	-6.7 ± 5.6	0.555
Physical functioning (PF)	-1.6 ± 1.7	-1.9 ± 1.8	0.742
Role limitation (RL)	-0.7 ± 2.4	-1.5 ± 2.6	0.451
Sleep	-2.3 ± 2.6	-1.9 ± 1.9	0.923
Social functioning (SF)	-1.6 ± 2.5	-2.0 ± 2.6	0.845
Emotions (E)	-3.0 ± 3.3	-5.5 ± 3.2	0.019*
Overall health (OH)	-0.6 ± 0.7	-0.6 ± 0.9	0.833
Absenteeism	-0.3 ± 1.0	-0.1 ± 0.3	0.679

Values were demonstrated in mean ± SD, *compared between groups

Statistical analysis: Wilcoxon's rank sum test

3.4 Objective assessments

3.4.1 Nasal airway resistance (NAR)

There was no changes of NAR after treatment in both groups shown in Table 3.14

Table 3.14 Mean NAR at week 0 and 4 in both groups

	Shallot		**Placebo**		***p*-value between groups (week 4)**
	Week 0	**Week 4**	**week 0**	**Week 4**	
NAR (Pa/cm^3/s)	0.3 ± 0.2	0.4 ± 0.4	0.2 ± 0.1	0.3 ± 0.2	0.435
***p*-value within group**	0.711		0.162		

Values were demonstrated in mean ± SD

Statistical analysis: Wilcoxon's signed rank test (within group), Wilcoxon's rank sum test (between groups)

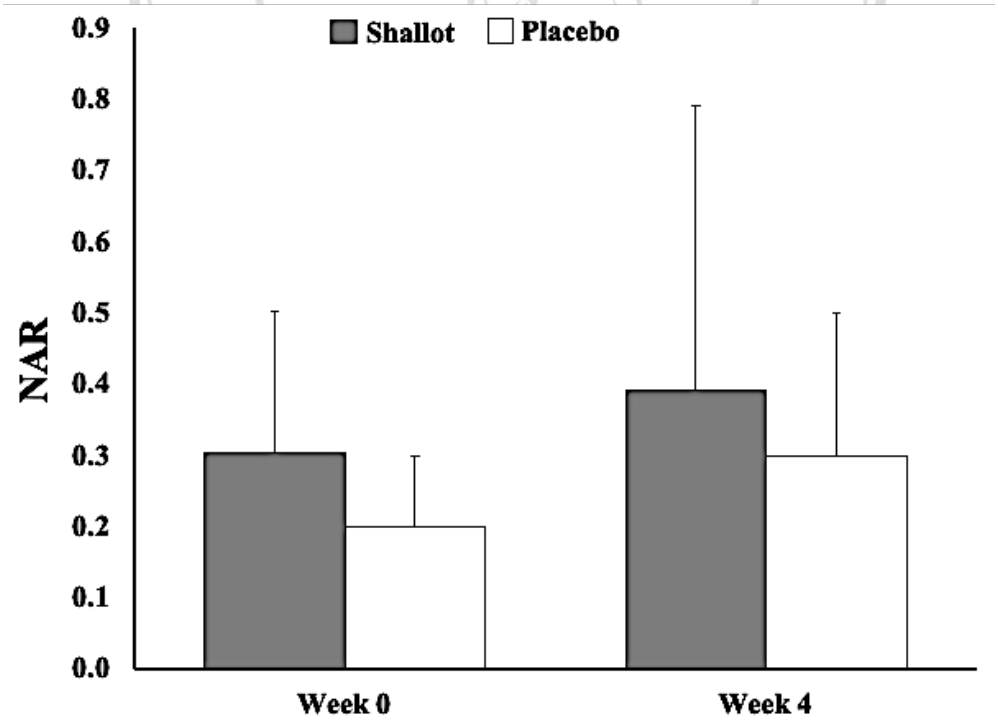

Figure 3.20 NAR at 75 Pa/cm^3/s at week 0 and 4

3.4.2 Nasal cytology

The results of nasal cytology that counted the number of cells after 2 and 4 weeks of treatment was no statistical difference as compared with week 0 in both groups. Lymphocyte and macrophage were not found at week 0 in both groups (Table 3.15). Similarly, the result of mean changes in the cells at week 2 and 4 was no statistical difference between groups (Table 3.16).

Table 3.15 Mean number of cells from nasal cytology at week 2 and 4 in both groups

Cells	**Shallot**			**Placebo**		
	Week 0	**Week 2**	**Week 4**	**week 0**	**Week 2**	**Week 4**
Neutrophils	0.4 ± 1.2	0.2 ± 0.9	0.7 ± 1.3	1.7 ± 3.2	0.2 ± 0.6	0.8 ± 2.0
p-value	-	1.000	0.952	-	0.054	0.054
Eosinophils	0.6 ± 1.3	0.2 ± 0.5	0.3 ± 0.6	2.1 ± 2.9	0.6 ± 0.9	0.4 ± 0.9
p-value	-	0.368	0.368	-	0.303	0.303
Basophils	0.1 ± 0.2	0 ± 0	0 ± 0	0.1 ± 0.4	0 ± 0	0 ± 0
p-value	-	0.368	0.368	-	0.135	0.135
Lymphocytes	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
p-value	-	1.000	1.000	-	1.000	1.000
Macrophages	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
p-value	-	1.000	1.000	-	1.000	1.000

Values were demonstrated in mean ± SD

Statistical analysis: Friedman test

Table 3.16 Mean changes from week 0 in cells from nasal cytology at week 0, 2, and 4 in both groups

Groups	Mean changes from week 0	
	Week 2	**Week 4**
Neutrophils		
Shallot	-0.2 ± 0.5	0.3 ± 1.0
Placebo	-1.5 ± 3.0	-0.9 ± 3.5
p-value	0.084	0.064
Eosinophils		
Shallot	-0.4 ± 1.3	-0.3 ± 1.4
Placebo	-1.6 ± 2.9	-1.7 ± 2.9
p-value	0.325	0.284
Basophils		
Shallot	-0.1 ± 0.2	-0.1 ± 0.2
Placebo	-0.1 ± 0.4	-0.1 ± 0.4
p-value	0.408	0.408
Lymphocytes		
Shallot	0 ± 0	0 ± 0
Placebo	0 ± 0	0 ± 0
p-value	1.000	1.000
Macrophages		
Shallot	0 ± 0	0 ± 0
Placebo	0 ± 0	0 ± 0
p-value	1.000	1.000

Values were demonstrated in mean ± SD

Statistical analysis: Wilcoxon's rank sum test

3.5 Safety assessments

3.5.1 Adverse events (AEs)

All adverse events (AEs) that occurred during treatment were presented in Table 3.17. No serious AE was noted. Listed of AE comprised dizziness, fatigue, headache, somnolence, rash, decreased strength of hair root, nausea, dyspepsia, dry mouth and throat. There was no difference of AEs between the shallot and placebo groups.

Table 3.17 AEs that occurred during the study in both groups

Adverse events	Shallot % (n = 25)	Placebo % (n = 22)	*p*-value
Central nervous system (CNS)			
Dizziness	16.0 (4)	9.1 (2)	0.479
Fatigue	24.0 (6)	18.2 (4)	0.627
Headache	4.0 (1)	18.2 (4)	0.116
Somnolence	40.0 (10)	54.5 (12)	0.319
Skin			
Rash	4.0 (1)	4.5 (1)	0.926
Decreased strength of hair root	4.0 (1)	9.1 (2)	0.476
Gastrointestinal (GI) system			
Nausea	4.0 (1)	13.6 (3)	0.237
Dyspepsia	12.0 (3)	22.7 (5)	0.329
Other			
Dry mouth and throat	4.0 (1)	9.1 (2)	0.476

Statistical analysis: Chi-square test

3.5.2 Physical examination and vital signs

The vital signs of subject in both groups at before and after treatment were showed in Table 3.18. There were not different before and after receiving treatments.

3.5.3 Laboratory investigation

Laboratory investigation included completed blood count and blood test for renal and liver function. There was not different before and after receiving treatments in both groups, shown in Table 3.19. After treatment, laboratory for safety assessment included Cr, AST, ALT was no statistical difference between groups, shown in Table 3.20.

Table 3.18 Vital signs at week 0 and 4 in both groups

Vital signs	Shallot (n = 18)		*p*-value	Placebo (n = 14)		*p*-value
	Week 0	Week 4		Week 0	Week 4	
Body mass index (kg/m^2)	24.3 ± 5.6	24.3 ± 5.5	0.248	23.6 ± 4.4	23.6 ± 4.3	0.917
Systolic blood pressure (mmHg)	115.1 ± 12.2	112.9 ± 10.3	0.432	111.6 ± 9.8	114.4 ± 13.1	0.220
Diastolic blood pressure (mmHg)	71.8 ± 8.6	68.7 ± 9.5	0.097	67.2 ± 9.5	64.5 ± 10.0	0.300
Pulse rate (beats/min)	75.8 ± 9.6	76.4 ± 9.6	0.878	78.4 ± 12.9	80.8 ± 12.4	0.550

Values were demonstrated in mean ± SD, statistical analysis: Wilcoxon's signed rank test

Table 3.19 Laboratory at week 0 and 4 in both groups

Laboratory	Shallot (n = 18)		*p*-value	Placebo (n = 14)		*p*-value
	Week 0	Week 4		Week 0	Week 4	
Hemoglobin (Hb) (M 14-18, F 12-15 g/dL)	13.0 ± 1.0	13.1 ± 1.2	0.491	13.0 ± 1.4	13.2 ± 1.5	0.777
Hematocrit (Hct) (M 40-54, F 35-49%)	39.4 ± 3.0	40.1 ± 3.5	0.127	39.4 ± 4.0	40.3 ± 4.4	0.414
Platelets (Plt) (140-440 x 10^3/μL)	285.7 ± 79.6	287.7 ± 6.7	0.879	288.7 ± 81.0	285.6 ± 7.6	0.975
White blood cell (WBC) (4.5-11.5 x 10^3/μL)	6.8 ± 1.6	6.7 ± 1.1	0.663	6.6 ± 2.9	7.7 ± 2.0	0.109
Neutrophil (40-70%)	53.7 ± 9.4	52.1 ± 8.4	0.687	56.1 ± 10.9	59.3 ± 11.6	0.362
Lymphocyte (20-40%)	36.7 ± 10.0	35.0 ± 10.6	0.522	32.9 ± 8.1	30.4 ± 7.4	0.299
Monocyte (2-11%)	5.9 ± 1.6	6.0 ± 2.4	0.634	5.9 ± 1.7	5.8 ± 2.2	0.625

Table 3.19 Laboratory at week 0 and 4 in both groups (continued)

Laboratory	Shallot (n = 18)		*p*-value	Placebo (n = 14)		*p*-value
	Week 0	Week 4		Week 0	Week 4	
Eosinophil (1-3%)	3.3 ± 1.7	4.7 ± 4.0	0.090	4.6 ± 3.3	4.4 ± 3.5	0.773
Basophil (0-2%)	0.4 ± 0.5	0.6 ± 0.5	0.180	0.6 ± 0.6	0.4 ± 0.5	0.180
Blood urea nitrogen (BUN) (10-20 mg/dL)	12.9 ± 4.5	12.4 ± 3.2	0.468	12.1 ± 3.5	11.9 ± 3.5	0.636
Creatinine (Cr) (0.6-1.3 mg/dL)	0.8 ± 0.1	0.8 ± 0.2	0.226	0.8 ± 0.2	0.8 ± 0.2	0.752
Aspartate aminotransferase (AST) level (5-34 U/L)	18.8 ± 5.3	20.9 ± 7.3	0.426	18.6 ± 5.7	19.6 ± 4.8	0.183
Alanine aminotransferase (ALT) level (0-55 U/L)	21.1 ± 14.4	23.2 ± 18.7	0.793	19.1 ± 14.3	18.9 ± 8.8	0.600

Values were demonstrated in mean ± SD, statistical analysis: Wilcoxon's signed rank test

Table 3.20 Percent mean changes from week 0 in laboratory for safety assessment in both groups

Laboratory	% mean changes from week 0		*p*-value
	Shallot	Placebo	
Creatinine (Cr) (mg/dL)	-0.3	-0.3	0.254
Aspartate aminotransferase (AST) level (U/L)	10.9	5.4	0.634
Alanine aminotransferase (ALT) level (U/L)	10.0	-1.0	0.621

Statistical analysis: Wilcoxon's rank sum test