PURE KERATIN

Summary of Cynatine® HNS Clinical Trial - Results on Hair

INTRODUCTION

• This study is a double blind Placebo controlled clinical study carried out on 50 male and 50 female subjects aimed at evaluating the efficacy of a food supplement, Cynatine® HNS, to help improve the conditions of hair.

• 5 tests were conducted to evaluate the impact of Cynatine in hair health.

I. HAIR PULL TEST

• The Hair Pull Test evaluates hair loss from every day activity such as washing and brushing. Gentle traction is provided to a total of approximately 60 hairs in three areas of the scalp and the total number of hairs extracted is counted.

• Healthy hairs in the anagen phase should remained rooted, while hairs in the telogen phase should be extracted.

Table 1a. Results of Hair-Pull Test on Overall subjects

	Study Group	female subjects)	
Pull Test Score	Cynatine [®] HNS group Mean ± SD	Placebo group Mean ± SD	p-value intergroup (Cynatine [®] HNS vs. Placebo)
Baseline	$12,9 \pm 0,3$	$13,0 \pm 0,3$	
Day 30	$9,8 \pm 0,2$	$11,9 \pm 0,3$	
Day 60	$7,2 \pm 0,2$	$11,6 \pm 0,2$	
Day 90	$6,9 \pm 0,1$	$10,9 \pm 0,2$	
Change to Baseline			
(%):			
Day 30	-23,9%	-7,5%	p < 0,001
Day 60	-43,2%	-9,4%	p < 0,001
Day 90	-45,5%	-15,8%	p < 0,001

Intergroup values determined by t-test of Student, p < 0.05 are significant

Table1b. Results of Hair-Pull Test on Female and Male subjects

	Study Groups							
	fe	emale subjec	ts	1	nale subject	s		
Pull Test Score	Cynatine group Mean ± SD	Placebo group ± SD Mean	p-value (Cynatine [®] HNS vs. Placebo)	Cynatine group Mean ± SD	Placebo group ± SD Mean	p-value (Cynatine [®] HNS vs. Placebo)		
Baseline	$13,1 \pm 0,4$	$12,8 \pm 0.3$		$12,8 \pm 0,4$	$13,2 \pm 0,4$			
Day 30	$9,6 \pm 0,3$	$11,5 \pm 0,4$		$9,9 \pm 0,3$	$12,4 \pm 0,4$			
Day 60	$6,9 \pm 0,3$	$11,5 \pm 0,2$		$7,5 \pm 0,2$	$11,8 \pm 0,3$			
Day 90	$7,0 \pm 0,2$	$10,6 \pm 0,3$		$6,9 \pm 0,1$	$11,1 \pm 0,3$			
Change to Baseline					,			
<u>(%)</u> :								
Day 30	-25,8%	-9,2%	p < 0,001	-21,9%	-5,7%	p <0,001		
Day 60	-46,2%	-9,0%	p < 0,001	-40,1%	-9,9%	p <0,001		
Day 90	-45,8%	-16,3%	p < 0,001	-45,2%	-15,4%	p <0,001		

Intergroup values determined by t-test of Student, p < 0.05 are significant

Figure 1a. : Results of Hair Pull Test for overall subjects; mean % reduction from baseline for Cynatine® HNS and Placebo.

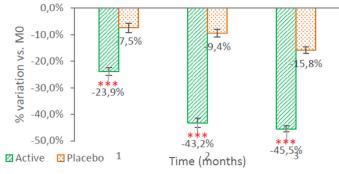


Figure 1b. : Hair pull test for female subjects; mean % reduction from baseline for Cynatine® HNS and Placebo

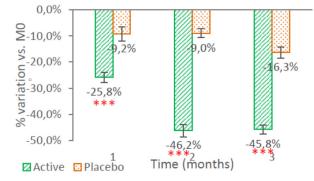
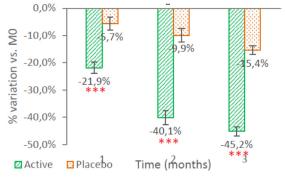


Figure 1c. : Hair pull test for male subjects; mean % reduction from baseline for Cynatine® HNS and Placebo



*** p < 0.001 between groups to baseline

Conclusion for overall population and in female and male groups:

• Cynatine[®] HNS reduced hair loss around 3 times more than Placebo at 30, 60 and 90 days.

• Cynatine® HNS showed a statistically significant decrease in hair loss vs. Placebo at 30, 60 and 90 days with p value < 0.001.

Reduced hair loss from everyday activities.
Reduced hair loss from everyday activities can be seen even within 30 days.

Supports Healthy Hair Growth.

II. ANAGEN/TELOGEN PHASE HAIR TEST

• In order to measure the number of hairs in the Anagen and Telogen phase of the hair cycle a 1.8cm2 patch of hair was shaved and dyed for contrast.

• Photos were taken immediately after shaving and then again after 2 days using a close-up digital camera.

• Computer software then analyzed the two pictures and could determine how many hair were growing (Anagen phase) and how many hair died (Telogen phase).

Table 2a. Results of Anagen/Telogen Phase Test on overall subjects

	Study Group Overall (male + female subjects)							
Anagen / Telogen score	Cynatine [®] HNS group Mean ± SD		Placebo grou	p-value (Cynatine®				
50010	Anagen	Telogen	Anagen	Telogen	HNS vs. Placebo)			
Baseline	$72,3\% \pm 0,1$	$27,7\%\pm0,1$	$72,8\% \pm 0,1$	$27,2\% \pm 0,1$				
Day 90	$84,1\%\pm0,2$	$15,9\% \pm 0,2$	$75,3\% \pm 0,1$	$24,7\% \pm 0,1$				
Change to Baseline								
<u>(%)</u> :								
Day 90	+11,8%	-11,8%	+2,5%	-2,5%	p < 0,001			

Intergroup values determined by t-test of Student, p < 0.05 are significant.

Table 2b. Results of Anagen/Telogen Phase Test on female and male subjects

female subjects				male subjects						
Anagen / Telogen score		e [®] HNS ean ± SD		o group ± SD	p-value (active		e [®] HNS ean ± SD		o group ± SD	p-value (active vs.
	Anagen	Telogen	Anagen	Telogen	vs. Placebo)	Anagen	Telogen	Anagen	Telogen	Placebo)
Baseline	72,9% ±0,2	27,1% ±0,2	73.0% ± 0.1	27.0% ± 0,1		71,8% ±0,2	28,2% ± 0,2	72,7% ±0,2	27.3% ± 0,2	
Day 90	85,3% ±0,2	14,7% ±0,2	75.5% ± 0,1	24,5% ± 0,1		82.9% ± 0,2	17.1% ± 0,2	75.1% ± 0,1	24,9% ± 0,1	
Change to Baseline (%):					p < 0,001					p < 0,001
Day 90	+12,4%	-12,4%	+2,5%	-2,5%		+11,1%	-11,1%	+2,4%	-2,4%	

Intergroup values determined by t-test of Student, p < 0.05 are significant.

Figure 2a. Anagen/Telogen Phase Test for overall subjects ; mean % reduction from baseline for Cynatine® HNS and Placebo



Figure 2b. Anagen/Telogen Phase Test for female subjects ; mean % reduction from baseline for Cynatine® HNS and Placebo

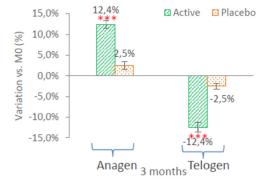
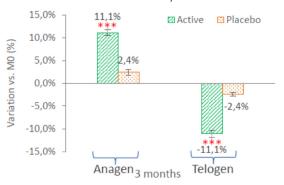


Figure 2c. Anagen/Telogen Phase Test for male subjects ; mean % reduction from baseline for Cynatine[®] HNS and Placebo



Conclusion for overall population and in female and male groups:

• Cynatine[®] HNS increases the number of hair in the Anagen phase and reduces the number of hair in Telogen phase after 90 days.

• Cynatine® HNS vs. Placebo showed results that were statistically very significant at 90 days on the global population as well as on men and women.

• Cynatine[®] HNS's effect over Placebo was greater than 4.5 times more for all groups.

✓ Cynatine[®] HNS supports healthy hair growth

III. AMINO ACID ANALYSIS OF HAIR

• Hair samples are taken from individuals and their amino acid profiles are analyzed by reverse phase liquid chromatography (results reported as % of total protein content).

• The quantities of the important amino acids which play a role in hair health (Serine,Glutamic Acid, Cystine and Methionine) have been measured below:

Table 3a. Results of the amino acid test on overall subjects

				Study Gro	up Overall	up Overall			
		Cynati	ne® HNS			Placebo			p value between
Amino Acid Score	Serine	Glutamic Acid	Cystine	Methionine	Serine	Glutamic Acid	Cystine	Methionine	groups (Cynatine®
		Mean %	± SD %			Mean %	± SD %		HNS vs. Placebo) :
Baseline	$11,0\pm0,4$	$14,3 \pm 0,4$	$17,4 \pm 0,4$	$1,1\pm0,1$	$11,3 \pm 0,4$	$13,9 \pm 0,5$	$17,8 \pm 0,5$	$1,2 \pm 0,1$	
Day 90	$15{,}4\pm0{,}5$	$18,1\pm0,4$	$26,8\pm0,6$	$4,7 \pm 0,2$	$11,7\pm0,3$	$14,1\pm0,5$	$16,9\pm0,4$	$1,2 \pm 0,1$	
Change to Baseline:									for all values p <
Day 90	+4,5%	+3,8%	+9,4%	+3,6%	+0,4%	+0,2%	-0,8%	+0,0%	0,001
p value (vs. baseline)	p < 0,001	p < 0,001	p < 0,001	p < 0,001	n.s.	n.s.	n.s.	n.s.	

Intragroup and intergroup values determined by RM-ANOVA and t-test of Student, p < 0.05 are significant.

Table 3b. Results of the amino acid test on female subjects

		Study Group female subjects							
Amino Acid	Cynatine® HNS Placebo					p value between			
Score	Serine	Glutamic Acid	Cystine	Methionine	Serine	Glutamic Acid	Cystine	Methionine	groups (Cynatine® HNS
		Mean 4	% ± SD %			Mean % ± SD %			vs. Placebo) :
Baseline	$11,1\pm0,6$	$14,5\pm0,5$	$17,1\pm0,5$	$1,1 \pm 0,1$	$11,5\pm0,5$	$14,0\pm0,7$	$17,6\pm0,6$	$1,2 \pm 0,1$	
Day 90	15,9 ± 0,8	18,2 ± 0,6	27,0 ± 0,8	$4,7 \pm 0,3$	11,8 ± 0,4	$14,2\pm0,8$	16,9 ± 0,6	$1,3 \pm 0,1$	
Change to Baseline:									for all values p < 0.001
Day 90	+4,7%	+3.7%	+9,9%	+3.5%	+0,3%	+0,2%	-0,8%	0,1%	\$ 0,001
p value (vs. baseline)	p < 0,001	p < 0,001	p < 0,001	p < 0,001	n.s.	n.s.	n.s.	n.s.	

Intragroup and intergroup values determined by RM-ANOVA and t-test of Student, p < 0.05 are significant.

Table 3c. Results of the amino acid test on male subjects

	Study Group male subjects								
		Cynatine [®] HNS				Placebo			
Amino Acid Score	Serine	Glutamic Acid	Cystine	Methionine	Serine	Glutamic Acid	Cystine	Methionine	between groups (Cvnatine®
		Mean 9	% ± SD %			Mean 9	% ± SD %		HNS vs. Placebo) :
Baseline	$10,8 \pm 0,5$	14,1 ± 0,6	17,7 ± 0,6	$1,1\pm0,1$	11,1 ± 0,5	13,9 ± 0,6	17,9 ± 0,7	$1,1\pm0,1$	
Day 90	$15,0 \pm 0,7$	$18,1 \pm 0,6$	$26,6\pm0,8$	$4,8 \pm 0,3$	$11,5 \pm 0,5$	$14,1\pm0,7$	$17,0 \pm 0,6$	$1,2\pm0,1$	for all
Change to Baseline:									values P < 0,001
Day 90	+4,3%	+4,0%	+8,9%	+3,7%	+0,4%	+0,2%	-0,9%	0,1%	
p value (vs. baseline)	p < 0,001	p < 0,001	p < 0,001	p < 0,001	n.s.	n.s.	n.s.	n.s.	

Intragroup and intergroup values determined by RM-ANOVA and t-test of Student, $p < 0.05 \mbox{ are significant.}$



Figure 3a. Serine Content – Overall subject

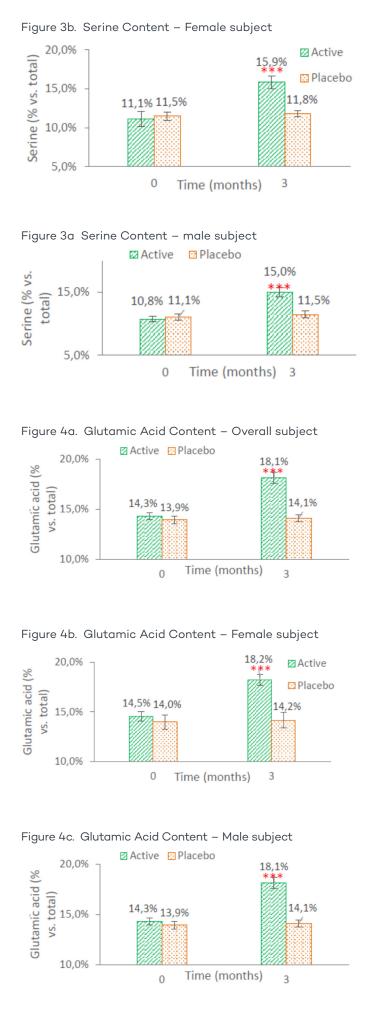


Figure 5a. Cystine Content – Overall subject



Figure 5b. Cystine Content – Female subject

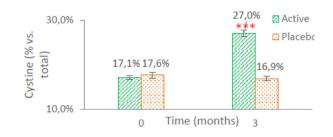


Figure 5c. Cystine Content – Male subject



Figure 6a. Methionine Content – Overall subject

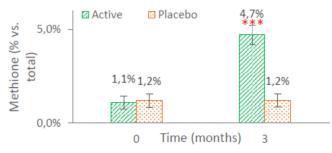
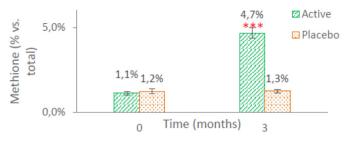
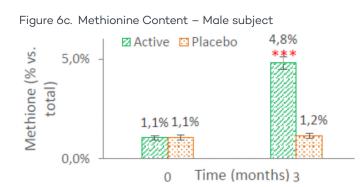


Figure 6b. Methionine Content - Female subject





p < 0.001 for all amino acids content as variation vs MO only in Cynatine® HNS group.

Figure 7a. Mean % change in amino acid profil after 90 days – Overall subjects

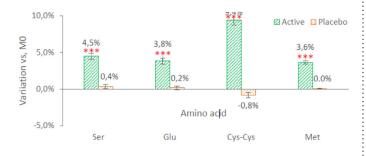
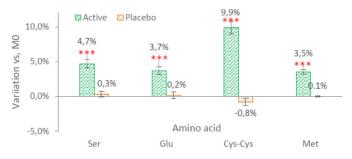
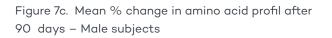
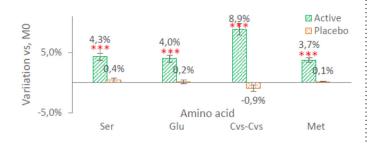


Figure 7b. Mean % change in amino acid profil after 90 days – Female subjects







*** p < 0.001 between groups to baseline

Conclusion for overall population and in female and male groups:

• Cynatine® HNS increases the amino acid content of Serine, Glutamic acid, Cystine and Methionine after 90 days.

• Cynatine® HNS showed results that were statistically significant versus baseline and versus Placebo at 90 days.

• The ability of the hair to absorb the amino acids from Cynatine® HNS shows its bioactivity.

Cynatine[®] HNS supports healthy hair growth.
 Cynatine[®] HNS improves the structure of the hair.
 Cynatine[®] HNS is bioactive.

IV. RESISTANCE TO TRACTION

• The strength of the hair is measured by dynamometer and recorded in centiNewtons.

• The stronger the hair, the more force it will take to break.

Table 4a. Results of the resistance to traction test on Overall subjects

D	Study Grou (male + fema	p-value (Cynatine®	
Resistance to traction score	Cynatine [®] HNS group Mean ± SD	Placebo group Mean ± SD	HNS vs. Placebo)
Baseline	71,7 cN ± 1,1	$71,2 \text{ cN} \pm 1,1$	1
Day 90	78,1 cN ± 1,1	$71,6 \text{ cN} \pm 1,1$	
Change to Baseline (cN):			
Day 90	+6,3 cN	+0,4 cN	p < 0,001
p value (vs. baseline)	p < 0,001	n.s.	

Intragroup and intergroup values determined by RM-ANOVA and t-test of Student, p < 0.05 are significant.

Table 4b. Results of the resistance to traction test on Female subjects

	Study Group f	emale subjects	p-value (Cynatine [®] HNS vs.
Resistance to traction score	Cynatine [®] HNS group Mean ± SD	Placebo group Mean ± SD	Placebo)
Baseline	73,1 cN ± 1,4	71,7 cN ± 1,6	1
Day 90	79,4 cN ± 1,5	72,7 cN ± 1,5	
Change to Baseline (cN):			
Day 90	+6,3 cN	+0,9 cN	p < 0,001
p value (vs. baseline)	p ≤ 0,001	n.s.	

Intragroup and intergroup values determined by RM-ANOVA and t-test of Student, p < 0.05 are significant.

Table 4c. Results of the resistance to traction test on Male subjects

Resistance to traction	Study Group	male subjects p-value (Cynatine®		
score	Cynatine [®] HNS group Mean ± SD	Placebo group Mean ± SD	vs. Placebo)	
Baseline	70,4 cN ± 1,6	70,7 cN ± 1,6		
Day 90	76,8 cN ± 1,7	70,5 cN ± 1,7		
Change to Baseline (cN):				
Day 90	+6,4 cN	- 0,1 cN	p < 0,001	
p value (vs. baseline)	p < 0,001	n.s.		

Intragroup and intergroup values determined by RM-ANOVA and t-test of Student, $p < 0.05 \mbox{ are significant.}$

Figure 8a. Hair resistance to traction results for Cynatine® HNS and Placebo – Overall Subjects

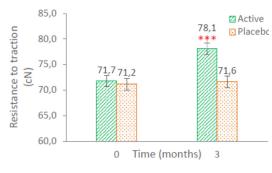


Figure 8b. Hair resistance to traction results for Cynatine® HNS and Placebo – Female Subjects

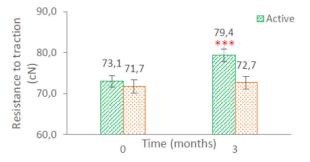
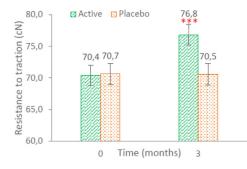


Figure 8c. Hair resistance to traction results for Cynatine® HNS and Placebo – Male Subjects



*** p < 0.001 within group to baseline

Figure 9a. Mean variation vs. MO in resistance to traction for Cynatine® HNS and Placebo – Overall subjects

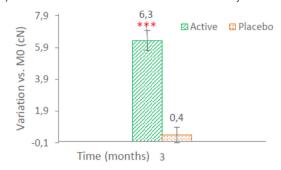


Figure 9b. Mean variation vs. MO in resistance to traction for Cynatine® HNS and Placebo – Female subjects

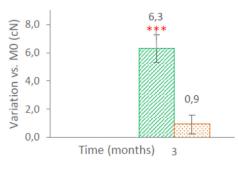
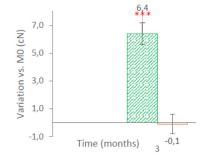


Figure 9c. Mean variation vs. MO in resistance to traction for Cynatine® HNS and Placebo – Male subjects



*** p < 0.001 between groups to baseline

Conclusion for overall population and in female and male groups:

• Cynatine[®] HNS increases the strength of hair (approximately 9% in all groups) after 90 days.

• Cynatine® HNS showed results that were statistically very significant to both baseline and Placebo at 90 days.

• The demonstrated effect of Cynatine HNS is clearly superior to that demonstrated by the Placebo.

- ✓ Cynatine[®] HNS supports healthy hair.
- Cynatine[®] HNS improves the structure of hair.
- ✓ Cynatine[®] HNS improves the strength of hair.

V. HAIR BRIGHTNESS ANALYSIS

• This data was measured by clinical evaluation by a trained clinician.

• The condition of the hair is given a numerical value based on the following scale:

- 1: Hair is dull and devoid of brightness.
- 2: Hair is basically dull and not so bright.
- 3: Hair is shiny and bright.

subjects			
	Study Group	o overall (male +	female subjects)
Hair brightness score	Cynatine [®] HNS group	Placebo group	p-value intergroup (Cynatine [®] HNS vs. Placebo)
Change to Baseline			
<u>(%)</u> :			
Day 30	30%	8%	p<0,01
Day 60	88%	20%	p<0,001
Day 90	92%	30%	p<0.001

Table 5a. Results of the hair brightness analysis on Overall

Intergroup determine by t-test of Student, values with $\rm p < 0.05~are$ significant.

Table 5b. Results of the hair brightness analysis on Female subjects

	Study	Group fema	le subjects
Hair brightness score	Cynatine [®] HNS group	Placebo group	p-value intergroup (Cynatine [®] HNS vs. Placebo)
Change to Baseline			
<u>(%)</u> :			
Day 30	32%	8%	p<0,05
Day 60	88%	20%	p<0,001
Day 90	92%	28%	p<0,001

Intergroup determine by t-test of Student, values with $\rm p$ < 0.05 are significant.

Table 5c. Results of the hair brightness analysis on Male subjects

	Study Group male subjects		
Hair brightness score	Cynatine® HNS group	Placebo group	p-value intergroup (Cynatine [®] HNS vs. Placebo)
Change to Baseline			
<u>(%)</u> :			
Day 30	28%	8%	n.s.
Day 60	88%	20%	p<0,001
Day 90	92%	32%	p<0,001

Intergroup determine by t-test of Student, values with $\rm p < 0.05$ are significant.

Figure 10a. Mean % change in hair brightness for Cynatine® HNS and Placebo – Overall subjects

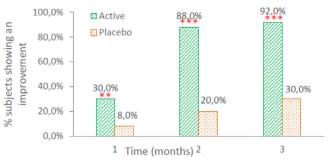


Figure 10b. Mean % change in hair brightness for Cynatine® HNS and Placebo – Female subjects

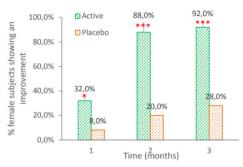
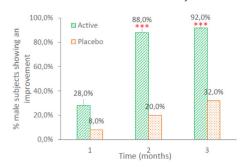


Figure 10c. Mean % change in hair brightness for Cynatine[®] HNS and Placebo – Male subjects



Conclusion for overall population and in female and male groups:

• Cynatine® HNS increases the shine and brightness of hair after 30 days.

• Cynatine® HNS showed results that were statistically significant to the baseline and the Placebo at 30, 60 and 90 days.

✓ Cynatine[®] HNS supports healthy hair.

 Cynatine[®] HNS improves the shine and brightness of hair.

VI. GENERAL CONCLUSION ON HAIR STUDY

• This clinical study demonstrates the effect of Cynatine® HNS (500 mg/day) in improving hair conditions.

• The product was effective in improving hair conditions at all experimental monitored checkpoints.

• The variations obtained in the Cynatine® HNS group are statically significant from the variation obtained in the Placebo group.

• Product effects on the measured parameters were comparable between male and female subjects.

• Cynatine contributes to reduced hair loss from everyday activities.

• Cynatine is bioavailable.

• Cynatine supports healthy hair and healthy hair growth.

• Cynatine improves the structure and the strength of hair.

• Cynatine improves the shine and brightness of hair.