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REVIEWS OF TREATMENT STUDIES

Electromagnetic fields applied to the reduction of abdominal obesity

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Abstract

Introduction: According to various researches, abdominal obesity increases the risks of cancers or cardio-vascular diseases. *Objective:* To evaluate the reduction of waistline and the evolution of biological parameters on patients after 12 sessions of a new medical device called REDUSTIM® associating alternate low frequency electromagnetic fields and controlled micropressure. *Methods:* Two studies were made: a double-blind randomized study performed on 28 patients with a waistline > 88 cm/35 inches for women and > 102 cm/40 inches for men for a period of 6 weeks and a functional analysis on DNA chips performed on 11 patients showing proven overweight. *Results:* Following our studies a statistically significant reduction of waistline of more than 6 cm after 12 sessions has been observed, and the biological assessments performed before and after the treatments showed both a highly significant reduction of transaminases level and the device mechanism on the stimulation of insensitive muscle contractions. *Conclusions:* Facing an alarming increase in overweight and obesity and considering the current therapeutic gear offering various results, it seems interesting to propose an efficient technique for the reduction of abdominal obesity. The clinical study demonstrated the safety and efficiency of the device for the reduction of abdominal obesity. Treatment showed itself efficient with patients who were not committed to any weight loss program.

Key Words: *electromagnetic fields, low frequency, abdominal obesity, lipolysis, DNA chips, waistline, genes activity*

Introduction

Abdominal obesity keeps increasing worldwide. According to a survey of bodyshapes conducted in the United Kingdom in 1951, a woman's average waistline was 70 cm. A 3-D survey carried out by SizeUK in 2004 found the average woman had a waist measurement of 86 cm.

Experts are worried that the increase in waistline and obesity will lead to an increased number of health problems.

Abdominal obesity increases the risks of cancers or cardio-vascular diseases (1): obesity from the lower part of the body (buttocks, thighs) is less dangerous for health than abdominal obesity (belly), which gives evidence of the presence of fat around viscera.

Waistline also reveals the location of visceral fat, which plays a key role in cardio-vascular or cancer associated pathologies. It is one of the major determining factors of the metabolic syndrome (2).

The basic principles for the reduction of visceral fat are: a regular physical activity, a healthier diet, a reduced consumption of salt, a decreased consumption of carbohydrates and a reduction of the waistline.

The use of alternate low-frequency electromagnetic fields in order to induce a lipolytic effect (reduction of adipose tissue) is a genuine technique that was first developed in the 1990s by Comfort Harmony®, a company specialized in such development.

This process was patented and enabled the development of equipment called BodySculptor®, launched on the market by Cosmosoft® in 2002.

With 9 years of efficiency, Cosmosoft® which was very concerned about bringing a complementary tool for the care of abdominal obesity, decided, thanks to a new device, to promote its patented technique in the medical field.

Material and methods

A patented technology

The technology is composed of a device and an integral suit covering a large part of the body (from the feet up to the celiac plexus).

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A magnetic fields generator transfers the energy to inductors located in the integral suit at the level of the target zones (abdomen, external parts of the thighs, internal parts of the knees, calves) while the six cells of the suit induce an upward pressure to ensure an effective drainage.

Considering the purpose of the study, the numbers of magnetic fields inductors has been increased by 50% on the abdominal part to ensure better results on this targeted area.

The device favours a significant and selective reduction of fatty mass thanks to a stimulation of lipolytic biological mechanisms with the combined action of low-frequency electromagnetic fields and controlled cutaneous micro-pressure.

Protocol

In October 2009, a double blind randomized study (3) was edited by Dr. Rodi Courie (Endocrinology, Metabolic Department, Hôpital La Pitié Salpêtrière, Inserm U939) and performed by Dr. Ghislaine Beilin and Dr. Florence Benichoux, and the recruitment took place with nine doctors from Paris: three practitioners specialized in nutrition, one phlebologist, one aesthetic physician, four general practitioners.

Twenty-eight volunteers participated in this study and were randomized as follows: 15 subjects in the 'tested equipment' group (device associating low frequency magnetic fields and controlled cutaneous pressure), and 13 subjects in the 'Placebo' group (device that wasn't generating any waves but with a controlled cutaneous pressure lowered to 65% of the active value). Both the volunteers and the recruited Clinical Research Associate (CRA), performing the anthropometric measurements before and after, were unable to distinguish the placebo machine from the treatment machine during the test.

Results and discussion

Mode of action

First, One main action based on the diffusion of alternate low-frequency magnetic fields in order to stimulate the fatty mass destocking. These waves present very particular properties that confer them a specific role on a lipolytic plan.

Indeed, several international studies highlighted a stimulation of membrane ATPases directly linked to calcium regulation, (usually called calcium pumps), in the presence of weak alternate magnetic fields (the low level of magnetic fields allows the implementation of the device without any risks for human body cells or any medical operating constraints), lower than 5 Gauss (corresponding to those of the device), and this at low electrical frequencies of 40–60 Hz (50 Hz for the device).

Ca^{2+}-ATPases are membrane enzymes located in the sarcoplasmic reticulum membrane of muscle cells where they represent 90% of membrane proteins.

Sarcoplasmic reticulum stores Ca^{2+} ions and the quick flow of these ions from the reticulum towards the sarcoplasm (muscle fibers cytoplasm) results in muscle contraction.

The magnetic stimulation of Ca^{2+} ions results in an increased ATPases activity, and therefore leads to the stimulation of the lipolytic activity towards fat cells stored at the muscular level without any additional efforts.

T0–T12	Tested equipment	Student test	Placebo equipment
Average waistline reduction	−6.07 cm	$p<0.01$	−1.81 cm
Average weight change	−0.63 kg	ns	+0.35 kg
Average glycaemia change	0 g/l	$p<0.05$	+0.11 g/l
Average ASAT change	−3.25 UI/l	ns	+1.50 UI/l
Average ALAT change	−7.08 UI/l	ns	+1.60 UI/l

The action thus consists in performing part of the energy expenditure cycle, but without making demands on muscular fibres, as if a physical activity was performed without any muscle fibre extension.

Moreover, the excess of ATP produced by this stimulation will be eliminated by the body in the same way as a sportsman would do it during a recovery cycle after an effort.

Second, a secondary draining action of controlled cutaneous pressure in order to facilitate the evacuation of fatty acids through systemic circulation and toxins elimination.

Treatment tolerance

Clinical and biological assessments performed before the first session and after the last one of the treatments didn't show any significant change in blood pressure SBP and DBP (annex 1), glycaemia (annex 2), triglycerides level (annex 3), total cholesterol level (annex 4) or LDL (annex 5) and HDL cholesterol (annex 6).

The other blood parameters, as well as blood pressure, didn't change statistically both in the 'tested equipment' group and in the 'Placebo' one. Nor did the weight, which varied unevenly between individuals, in the absence of any food rebalancing.

Furthermore, no significant side effects were noticed during this study test.

	EVALUATION OF SIDE EFFECTS	
	REDUSTIM® (15 people)	PLACEBO (13 people)
Dizziness	-	2
Headaches	-	3
Nausea	-	-
Abdominal pain	3	1
Tiredness	3	1
Sleeping disorders	-	1
TOTAL	6	8

Evolution of waistline

The main goal of this study was to evaluate the ability of the treatment to achieve a waistline reduction after 12 sessions on healthy overweight or obese volunteers that were not committed to any weight loss program.

Considering the waistline reduction as the main assessment criterion, the results were the following (full data presented in annex 7):

The waistline reduction appeared highly significant according to the Student's t-test in matched series. The slight weight change shows that the subjects respected the protocol, which specified that the subjects were asked not to modify their diet.

This study highlighted the specific waistline reduction, which involves an intra-abdominal fatty

Figure 1. Pictures before and after treatment.

mass reduction. Patients who participated in this study were selected according to their important waistline, but the other four criteria of the metabolic syndrome were almost normal.

Considering the results obtained, it clearly appears that the medical device, compared to the 'Placebo' one, enables a highly significant ($p < 0.01$) waistline reduction: −6.1 cm on average versus −1.8 cm for the 'Placebo' group.

Evolution of ASAT and ALAT Transaminases

Another key-point was highlighted in this study: the changes in hepatic transaminases levels (full data presented in annex 8).

Indeed, the hepatic transaminases (ASAT, ALAT) were analyzed in order to ensure that the circulating fatty acids released by the treatment were not stored in the liver (hepatic steatosis).

The results of the study not only made it possible to check that the released fatty acids were not stored in the liver, but on the contrary the ALAT levels booked a 23% reduction with tested equipment versus a reduction of 7% with the 'Placebo' group, and the ASAT levels booked a 13% reduction with tested equipment versus a reduction of 8% with the 'Placebo' group.

Comparison of ASAT/ALAT levels*		
	Tested equipment	
ASAT	T0: 25.17	T12: 21.92
ALAT	T0: 30.92	T12: 23.83
Placebo		
ASAT	T0: 18.80	T12: 20.30
ALAT	T0: 21.80	T12: 23.40

*REDUSTIM: results on 12 individuals / PLACEBO: results on 10 individuals.

These results are highly significant for the ALAT level at risk $\alpha = 0.10$ and are generally equally significant for the ASAT level at risk $\alpha = 0.12$. They demonstrate the positive action of the device on the liver in the process of discharging abdominal fat.

DNA chips study and CA^{2+} channels activation

The results of this double-blind, randomized study can be linked to those of the study performed in the same conditions, without any food rebalancing, on 'DNA chips'.

Functional analysis study performed by Dr Philippe Benech (4) from Prediguard Laboratories Inc. intended to identify, thanks to DNA chips technology, the potential effects of 12 sessions of tested equipment, on the activity of genes expressed in the peripheral blood of 11 subjects.

As a result, at the abdominal level, the magnetic fields trigger a stimulation of insensitive muscle contraction CA^{2+} calcium channels (annex 9 – network 1) (annex 10 – network 2) (annex 11 – network 3), which increases the production of Lipase HSL (annex 12 – network 4), thus resulting in the hydrolysis of triglycerides at the intramuscular level.

Biological mode of action of the treatment

Thanks to this new, so-called 'DNA chips' technology, the action mode of the device was explained in a consistent manner. The genetic expression profile from 11 patients treated with the device was analysed in the conditions of a traditional treatment of 12 sessions (3 sessions per week during 1 month).

The results highlighted a strong to significant response on the expression of 89 genes, common to all subjects, in 73% of the cases, in parallel to their waistline reduction.

Genes with a positive expression seem to target muscle cells, and it is very likely that the sessions induce imperceptible muscle contractions similar to those resulting from a sustained exercise.

The induced muscle contraction increases the activity of lipase (HSL), which favours the hydrolysis of intramuscular triglycerides.

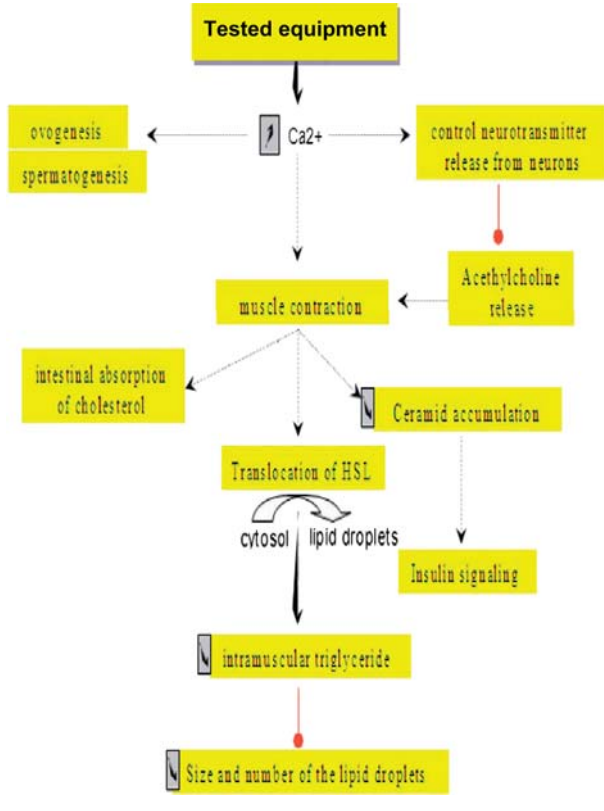

Figure 2. Biological mode of action of the treatment.

The device appears to act on the discharge of lipids naturally contained in the hypodermis layer, which further substantiates the use of this device for aesthetic purposes.

Discussion

In this study, several positive effects have been observed: the efficiency in the reduction of waistline for people suffering from abdominal obesity; the safety of the treatment; the good tolerance of the device; and the positive action on the process of discharging abdominal fat.

Moreover, we can notice that the treatment allows to take out patients of the metabolic syndrome: 5 volunteers out of 15 saw the waistline criterion, according to the definition of the metabolic syndrome, going back to a normal level (less than 88 cm for women and less than 102 cm for men) or being significantly reduced.

When three out of five criteria exceed the maximum tolerated value, there is an acute risk of a short or mid-term period of cardio-vascular or cancer associated pathologies.

Another study is currently processing to evaluate the abdominal fat concerned by the reduction, thanks to an Echo-Doppler method.

Finally, looking at the results that have been objectivized via the DNA Chips analysis concerning the ovogenesis and the spermatogenesis activation and noticing the knowledge around the links between visceral fats and infertility (5) (annex 13 – network 7), we are currently evaluating the action of the device on the fertility improvement on patients treated by the equipment. This study is currently supervised by Dr Vanessa Gallot (Pr. René FRYDMAN Department) at the Antoine Béclère Hospital in Clamart – France.

Conclusion

The results of this study clearly demonstrated that tested equipment treatment had a significant action on the waistline reduction and a positive action on lipids abnormally accumulated around internal organs or in muscles (especially on the waistline) granting it a positive role in healthcare.

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Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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   ii. Triglycerides level higher than 1.6 mmol/l
   iii. HDL cholesterol lower than 1.04 mmol/l for men, 1.29 mmol/l for women
   iv. Blood pressure higher than or equal to 130/85 mmHg or anti-hypertensive treatments Glycaemia (Empty stomach) greater than or equal to 6.1 mmol/l
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Annex 1

EVOLUTION OF SYSTOLIC BLOOD PRESSURE (SBP)

REDUSTIM			
15 volunteers	CALCULATION OF SYSTOLIC BLOOD PRESSURE (SBP)		
	SBP T0	SBP T12	T12-T0
1	121	126	5,00
2	130	128	-2,00
6	108	119	11,00
8	147	148	1,00
10	121	100	-21,00
11	113	128	15,00
13	135	140	5,00
14	142	140	-2,00
15	148	135	-13,00
17	144	141	-3,00
19	124	123	-1,00
20	133	125	-8,00
25	127	128	1,00
26	131	134	3,00
27	115	110	-5,00
Avg	129,27	128,33	-0,93
E-type	12,49	12,44	8,91
Var % / T0	x	-0,72	

PLACEBO			
13 volunteers	CALCULATION OF SYSTOLIC BLOOD PRESSURE (SBP)		
	SBP T0	SBP T12	T12-T0
3	155	137	-18,00
4	121	121	0,00
5	105	110	5,00
7	136	128	-8,00
9	125	126	1,00
12	141	124	-17,00
16	124	131	7,00
18	134	128	-6,00
21	119	120	1,00
22	105	122	17,00
23	120	108	-12,00
24	130	131	1,00
28	109	129	20,00
Avg	124,92	124,23	-0,69
E-type	14,48	8,21	11,61
Var % / T0	x	-0,55	

Comparison Tx vs T0		
REDUSTIM	SBP T0	SBP T12
Student *t* test, p=	x	0,691
Conclusion	x	dns

Comparison Tx vs. T0		
PLACEBO	SBP T0	SBP T12
Student *t* test / T0 : p=	x	0,833
Conclusion	x	dns

Comparison Tx vs. Tx (Redustim/Placebo)		
	T0 vs. T0	T12 vs. T12
Student *t* test / T0 : p=	0,402	0,321
Conclusion	dns	dns

Comparison (Tx-T0) vs. (Tx-T0)		
	T0 vs. T0	T12 vs. T12
Student *t* test / T0 : p=	x	0,951
Conclusion	x	dns

The comparative results of Redustim vs. Placebo with respect to systolic blood pressure are not significant.

EVOLUTION OF DIASTOLIC BLOOD PRESSURE (DBP)

REDUSTIM			
15 volunteers	CALCULATION OF DIASTOLIC BLOOD PRESSURE		
	DBP T0	DBP T12	T12-T0
1	79	84	5,00
2	90	86	-4,00
6	78	79	1,00
8	93	97	4,00
10	79	60	-19,00
11	71	78	7,00
13	95	88	-7,00
14	96	93	-3,00
15	109	87	-22,00
17	96	94	-2,00
19	72	72	0,00
20	89	83	-6,00
25	80	79	-1,00
26	85	85	0,00
27	83	93	10,00
Avg	86,33	83,87	-2,47
E-type	10,39	9,52	8,70
Var %/ T0	x	-2,86	

PLACEBO			
13 volunteers	CALCULATION OF DIASTOLIC BLOOD PRESSURE		
	DBP T0	DBP T12	T12-T0
3	99	89	-10,00
4	80	82	2,00
5	69	74	5,00
7	81	91	10,00
9	83	77	-6,00
12	81	87	6,00
16	84	87	3,00
18	86	79	-7,00
21	66	77	11,00
22	68	69	1,00
23	74	78	4,00
24	83	87	4,00
28	77	78	1,00
Avg	79,31	81,15	1,85
E-type	8,82	6,58	6,26
Var %/ T0	x	2,33	

Comparison Tx vs T0		
REDUSTIM	DBP T0	DBP T12
Student *t* test, p=	x	0,291
Conclusion	x	dns

Comparison Tx vs T0		
PLACEBO	DBP T0	DBP T12
Student *t* test / T0 : p=	x	0,308
Conclusion	x	dns

Comparison Tx vs Tx (Redustim/Placebo)		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	0,067	0,396
Conclusion	dns	dns

Comparison (Tx-T0) vs (Tx-T0) [Redustim/Placebo		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	x	0,150
Conclusion	x	dns

The comparative results of Redustim vs. Placebo with respect to diastolic blood pressure are not significant.

Annex 2

EVOLUTION OF GLYCEMIA*

REDUSTIM			
15 volunteers	CALCULATION OF GLYCEMIA*		
	GLY T0	GLY T12	T12-T0
1			
2	0,90	0,97	0,07
6	0,95	0,92	-0,03
8	0,94	1,07	0,13
10	0,79	0,81	0,02
11	1,07	0,90	-0,17
13			
14			
15	1,00	1,03	0,03
17	0,96	1,17	0,21
19	0,90	0,96	0,06
20	0,97	0,99	0,02
25	1,36	1,06	-0,30
26	1,16	1,01	-0,15
27	0,82	0,90	0,08
Avg	0,99	0,98	0,00
E-type	0,15	0,10	0,14
Var % / T0	x	-0,25	

PLACEBO			
13 volunteers	CALCULATION OF GLYCEMIA*		
	GLY T0	GLY T12	T12-T0
3	0,83	0,95	0,12
4			
5	0,92	0,98	0,06
7	0,89	1,03	0,14
9	0,83	0,88	0,05
12	1,02	1,10	0,08
16	0,88	0,88	0,00
18			
21	0,84	1,01	0,17
22	0,81	1,00	0,19
23			
24	0,90	0,93	0,03
28	0,95	1,16	0,21
Avg	0,89	0,99	0,11
E-type	0,06	0,09	0,07
Var % / T0	x	11,84	

Comparison Tx vs T0		
REDUSTIM	GLY T0	GLY T12
Student t test, p=	x	0,952
Conclusion	x	dns

Comparison Tx vs T0		
PLACEBO	GLY T0	GLY T12
Student test / T0 : p=	x	0,001
Conclusion	x	ds 0,01

Comparison Tx vs Tx (Redustim/Placebo)		
	T0 vs T0	T12 vs T12
Student t test / T0 : p=	0,076	0,814
Conclusion	dns	dns

Comparison (Tx-T0) vs (Tx-T0) [Redustim/Placebo		
	T0 vs T0	T12 vs T12
Student t test / T0 : p=	x	0,042
Conclusion	x	ds 0,05

* REDUSTIM : results on 12 individuals
PLACEBO : results on 10 individuals

The comparative results of Redustim vs Placebo with respect to glycemia are not significant.

Annex 3

EVOLUTION OF TRIGLYCERIDES*

REDUSTIM 15 volunteers	CALCULATION OF SYSTOLIC BLOOD PRESSURE (SBP)		
	SBP T0	SBP T12	T12-T0
1	121	126	5,00
2	130	128	-2,00
6	108	119	11,00
8	147	148	1,00
10	121	100	-21,00
11	113	128	15,00
13	135	140	5,00
14	142	140	-2,00
15	148	135	-13,00
17	144	141	-3,00
19	124	123	-1,00
20	133	125	-8,00
25	127	128	1,00
26	131	134	3,00
27	115	110	-5,00
Avg	129,27	128,33	-0,93
E-type	12,49	12,44	8,91
Var % / T0	x	-0,72	

PLACEBO 13 volunteers	CALCULATION OF SYSTOLIC BLOOD PRESSURE (SBP)		
	SBP T0	SBP T12	T12-T0
3	155	137	-18,00
4	121	121	0,00
5	105	110	5,00
7	136	128	-8,00
9	125	126	1,00
12	141	124	-17,00
16	124	131	7,00
18	134	128	-6,00
21	119	120	1,00
22	105	122	17,00
23	120	108	-12,00
24	130	131	1,00
28	109	129	20,00
Avg	124,92	124,23	-0,69
E-type	14,48	8,21	11,61
Var % / T0	x	-0,55	

Comparison Tx vs T0		
REDUSTIM	SBP T0	SBP T12
Student *t* test, p=	x	0,691
Conclusion	x	dns

Comparison Tx vs T0		
PLACEBO	SBP T0	SBP T12
Student *t* test / T0 : p=	x	0,833
Conclusion	x	dns

Comparison Tx vs Tx (Redustim/Placebo)		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	0,402	0,321
Conclusion	dns	dns

Comparison (Tx-T0) vs (Tx-T0) [Redustim/Placebo		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	x	0,951
Conclusion	x	dns

* REDUSTIM: results on 12 individuals
PLACEBO: results on 10 individuals

The comparative results of Redustim vs. Placebo with respect to triglycerides are not significant.

Annex 4

EVOLUTION OF TOTAL CHOLESTEROL (TC)*

REDUSTIM			
15 volunteers	CALCULATION OF TOTAL CHOLESTEROL (TC)*		
	TC T0	TC T12	T12-T0
1			
2	2,09	2,05	-0,04
6	2,04	1,99	-0,05
8	2,44	2,83	0,39
10	2,01	1,94	-0,07
11	1,96	1,80	-0,16
13			
14			
15	2,04	2,07	0,03
17	3,11	2,84	-0,27
19	1,97	1,84	-0,13
20	2,18	1,88	-0,30
25	1,67	2,22	0,55
26	2,93	2,95	0,02
27	1,62	1,64	0,02
Avg	2,17	2,17	0,00
E-type	0,45	0,45	0,25
Var % / T0	x	-0,04	

PLACEBO			
13 volunteers	CALCULATION OF TOTAL CHOLESTEROL (TC)*		
	TC T0	TC T12	T12-T0
3	1,72	1,69	-0,03
4			
5	1,42	1,63	0,21
7	2,16	2,09	-0,07
9	1,94	1,44	-0,50
12	2,14	2,76	0,62
16	2,47	2,23	-0,24
18			
21	1,32	1,55	0,23
22	1,87	1,95	0,08
23			
24	1,86	2,09	0,23
28	1,62	1,78	0,16
Avg	1,85	1,92	0,07
E-type	0,35	0,39	0,30
Var % / T0	x	3,73	

Comparison Tx vs T0		
REDUSTIM	TC T0	TC T12
Student *t* test, p=	x	0,991
Conclusion	x	dns

Comparison Tx vs T0		
PLACEBO	TC T0	TC T12
Student *t* test / T0 : p=	x	0,491
Conclusion	x	dns

Comparison Tx vs Tx (Redustim/Placebo)		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	0,083	0,184
Conclusion	dns	dns

Comparison (Tx-T0) vs (Tx-T0) [Redustim/Placebo		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	x	0,559
Conclusion	x	dns

* REDUSTIM : results on 12 individuals
PLACEBO : results on 10 individuals

The comparative results of Redustim vs. Placebo with respect to total cholesterol are not significant.

Annex 5

EVOLUTION OF HDL CHOLESTEROL*

REDUSTIM			
15 volunteers	CALCULATION OF HDL CHOLESTEROL*		
	HDL T0	HDL T12	T12-T0
1			
2	0,62	0,61	-0,01
6	0,56	0,57	0,01
8	0,72	0,74	0,02
10	0,50	0,51	0,01
11	0,72	0,59	-0,13
13			
14			
15	0,57	0,57	0,00
17	0,61	0,55	-0,06
19	0,68	0,59	-0,09
20	0,52	0,45	-0,07
25	0,44	0,41	-0,03
26	0,81	0,64	-0,17
27	0,59	0,66	0,07
Avg	0,61	0,57	-0,04
E-type	0,11	0,09	0,07
Var % / T0	x	-6,13	

PLACEBO			
13 volunteers	CALCULATION OF HDL CHOLESTEROL*		
	HDL T0	HDL T12	T12-T0
3	0,62	0,66	0,04
4			
5	0,52	0,61	0,09
7	0,80	0,78	-0,02
9	0,55	0,54	-0,01
12	0,53	0,58	0,05
16	0,64	0,47	-0,17
18			
21	0,42	0,44	0,02
22	0,63	0,61	-0,02
23			
24	0,65	0,71	0,06
28	0,46	0,47	0,01
Avg	0,58	0,59	0,00
E-type	0,11	0,11	0,07
Var % / T0	x	0,86	

Comparison Tx vs T0		
REDUSTIM	HDL T0	HDL T12
Student *t* test, p=	x	0,086
Conclusion	x	dns

Comparison Tx vs T0		
PLACEBO	HDL T0	HDL T12
Student *t* test / T0 : p=	x	0,830
Conclusion	x	dns

Comparison Tx vs Tx (Redusim/Placebo)		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	0,526	0,766
Conclusion	dns	dns

Comparison (Tx-T0) vs (Tx-T0) [Redusim/Placebo		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	x	0,171
Conclusion	x	dns

* REDUSTIM : results on 12 individuals
PLACEBO : results on 10 individuals

The comparative results of Redustim vs. Placebo with respect to HDL cholesterol are not significant.

Annex 6

EVOLUTION OF LDL CHOLESTEROL*

REDUSTIM			
15 volunteers	CALCULATION OF LDL CHOLESTEROL		
	LDL T0	LDL T12	T12-T0
1			
2	1,35	1,31	-0,04
6	1,39	1,34	-0,05
8	1,47	1,84	0,37
10	1,39	1,35	-0,04
11	1,15	1,07	-0,08
13			
14			
15	1,31	1,34	0,03
17	2,32	2,09	-0,23
19	1,13	1,11	-0,02
20	1,37	1,22	-0,15
25	1,09	1,59	0,50
26	1,97	2,11	0,14
27	0,85	0,89	0,04
Avg	1,40	1,44	0,04
E-type	0,40	0,39	0,21
Var % / T0	x	2,80	

PLACEBO			
13 volunteers	CALCULATION OF LDL CHOLESTEROL		
	LDL T0	LDL T12	T12-T0
3	0,72	0,77	0,05
4			
5	0,80	0,91	0,11
7	1,26	1,20	-0,06
9	1,25	0,82	-0,43
12	1,31	1,92	0,61
16	1,47	1,48	0,01
18			
21	0,82	1,00	0,18
22	1,13	1,21	0,08
23			
24	1,07	1,25	0,18
28	0,99	1,00	0,01
Avg	1,08	1,16	0,07
E-type	0,25	0,35	0,26
Var % / T0	x	6,84	

Comparison Tx vs T0		
REDUSTIM	LDL T0	LDL T12
Student *t* test, p=	x	0,529
Conclusion	x	dns

Comparison Tx vs T0		
PLACEBO	LDL T0	LDL T12
Student *t* test / T0 : p=	x	0,385
Conclusion	x	dns

Comparison Tx vs Tx (Redustim/Placebo)		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	**0,040**	0,092
Conclusion	ds 0,05	dns

Comparison (Tx-T0) vs (Tx-T0) [Redustim/Placebo		
	T0 vs T0	T12 vs T12
Student *t* test / T0 :p=	x	0,729
Conclusion	x	dns

* **REDUSTIM : results on 12 individuals**
PLACEBO : results on 10 individuals

The comparative results of Redustim vs. Placebo with respect to LDL cholesterol are not significant.

Annex 7

EVOLUTION OF WAISTLINE

REDUSTIM					
15 volunteers	WAISTLINE CALCULATION (in cm)				
	Waistline T0	Waistline T6	Waistline T12	T6-T0	T12-T0
1	83	78	77	-5,00	-6,00
2	97	94	92	-3,00	-5,00
6	87	84	79	-3,00	-8,00
8	95	94	92	-1,00	-3,00
10	89	87	87	-2,00	-2,00
11	87	77	78	-10,00	-9,00
13	109	105	105	-4,00	-4,00
14	108	104	98	-4,00	-10,00
15	109	107	106	-2,00	-3,00
17	106	100	96	-6,00	-10,00
19	98	96	94	-2,50	-4,00
20	112	109	103	-3,00	-9,00
25	116	111	109	-5,00	-7,00
26	102	99	97	-3,00	-5,00
27	86	81	80	-5,00	-6,00
Avg.	98,93	95,03	92,87	-3,90	-6,07
E-type	10,79	11,38	10,70	2,17	2,66
Var % / T0	x	-3,94	-6,13		

PLACEBO					
13 volunteers	WAISTLINE CALCULATION (in cm)				
	Waistline T0	Waistline T6	Waistline T12	T0	T12-T0
3	115	113	114	-2,00	-1,00
4	99	94	95	-5,00	-4,50
5	94	88	86	-6,00	-8,00
7	97	97	97	0,00	0,00
9	103	99	99	-4,00	-4,00
12	107	106	107	-1,00	0,50
16	112	111	110	-1,00	-2,50
18	101	98	100	-3,00	-1,00
21	93	89	92	-4,00	-1,00
22	88	88	88	0,00	0,00
23	87	82	86	-5,00	-1,00
24	98	97	98	-1,00	0,00
28	84	84	83	0,00	-1,00
Avg.	98,23	95,77	96,42	-2,46	-1,81
E-type	9,34	9,73	9,59	2,15	2,40
Var % / T0	x	-2,51	-1,84		

Comparison Tx vs T0			
REDUSTIM	Waistline T0	Waistline T6	Waistline T12
Student *t* test, p=	x	0,00001	0,0000004
Conclusion	x	sd 0,01	<<0,01

Comparison Tx vs T0			
PLACEBO	Waistline T0	Waistline T6	Waistline T12
Student *t* test/ T0 : p=	x	0,001	0,019
Conclusion	x	sd 0,01	ds 0,05

Comparison Tx vs Tx (Redustim Placebo)			
	T0 vs T0	T6 vs T6	T12 vs T12
Student *t* test/ T0 : p=	0,856	0,857	0,366
Conclusion	dns	dns	dns

Comparison (Tx-T0) vs (Tx-T0) [Redustim/Placebo			
	T0 vs T0	T6 vs T6	T12 vs T12
Student *t* test/ T0 : p=	x	0,091	0,0002
Conclusion	x	dns	<<0,01

The comparative results of Redustim vs. Placebo with respect to waistline are highly significant (p<0.01).

Annex 8

EVOLUTION OF ASAT TRANSAMINASES*

REDUSTIM			
15 volunteers	CALCULATION OF ASAT TRANSAMINASES		
	ASAT T0	ASAT T12	T12-T0
1			
2	18	18	0,00
6	12	13	1,00
8	37	32	-5,00
10	31	34	3,00
11	39	20	-19,00
13			
14			
15	27	27	0,00
17	16	13	-3,00
19	44	22	-22,00
20	24	18	-6,00
25	17	25	8,00
26	20	22	2,00
27	17	19	2,00
Avg	25,17	21,92	-3,25
E-type	10,42	6,64	8,89
Var % / T0	x	-12,91	

PLACEBO			
13 volunteers	CALCULATION OF ASAT TRANSAMINASES		
	ASAT T0	ASAT T12	T12-T0
3	16	17	1,00
4	24	29	5,00
5	21	18	-3,00
7	16	18	2,00
9	22	17	-5,00
12	13	17	4,00
16	18	20	2,00
18			
21	16	17	1,00
22	19	22	3,00
23			
24	23	28	5,00
28			
Avg	18,80	20,30	1,50
E-type	3,61	4,62	3,27
Var % / T0	x	7,98	

Comparison Tx vs T0		
REDUSTIM	ASAT T0	ASAT T12
Student *t* test, p=	x	0,232
Conclusion	x	dns

Comparison Tx vs T0		
PLACEBO	ASAT T0	ASAT T12
Student *t* test / T0 : p=	x	0,181
Conclusion	x	dns

Comparison Tx vs Tx (Redustim/Placebo)		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	0,081	0,524
Conclusion	dns	dns

Comparison (Tx-T0) vs (Tx-T0) [Redustim/Placebo		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	x	0,126
Conclusion	x	ds

*** REDUSTIM : results on 12 individuals**
PLACEBO : results on 10 individuals

The comparative results of Redustim vs. Placebo with respect to ASAT transaminases are significant to risk a = 0.12.

EVOLUTION OF ASAT TRANSAMINASES*

REDUSTIM			
15 volunteers	CALCULATION OF ASAT TRANSAMINASES		
	ASAT T0	ASAT T12	T12-T0
1			
2	18	18	0,00
6	12	13	1,00
8	37	32	-5,00
10	31	34	3,00
11	39	20	-19,00
13			
14			
15	27	27	0,00
17	16	13	-3,00
19	44	22	-22,00
20	24	18	-6,00
25	17	25	8,00
26	20	22	2,00
27	17	19	2,00
Avg	25,17	21,92	-3,25
E-type	10,42	6,64	8,89
Var % / T0	x	-12,91	

PLACEBO			
13 volunteers	CALCULATION OF ASAT TRANSAMINASES		
	ASAT T0	ASAT T12	T12-T0
3	16	17	1,00
4	24	29	5,00
5	21	18	-3,00
7	16	18	2,00
9	22	17	-5,00
12	13	17	4,00
16	18	20	2,00
18			
21	16	17	1,00
22	19	22	3,00
23			
24	23	28	5,00
28			
Avg	18,80	20,30	1,50
E-type	3,61	4,62	3,27
Var % / T0	x	7,98	

Comparison Tx vs T0		
REDUSTIM	ASAT T0	ASAT T12
Student *t* test, p=	x	0,232
Conclusion	x	dns

Comparison Tx vs T0		
PLACEBO	ASAT T0	ASAT T12
Student *t* test / T0 : p=	x	0,181
Conclusion	x	dns

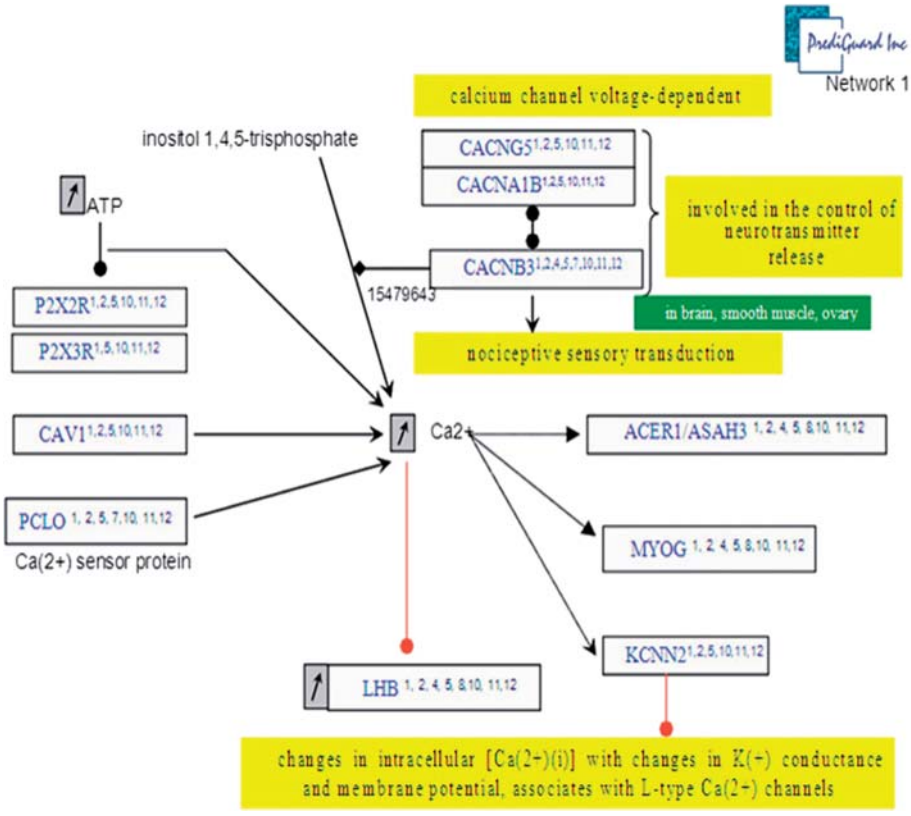
Comparison Tx vs Tx (Redustim/Placebo)		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	0,081	0,524
Conclusion	dns	dns

Comparison (Tx-T0) vs (Tx-T0) [Redustim/Placebo		
	T0 vs T0	T12 vs T12
Student *t* test / T0 : p=	x	0,126
Conclusion	x	ds

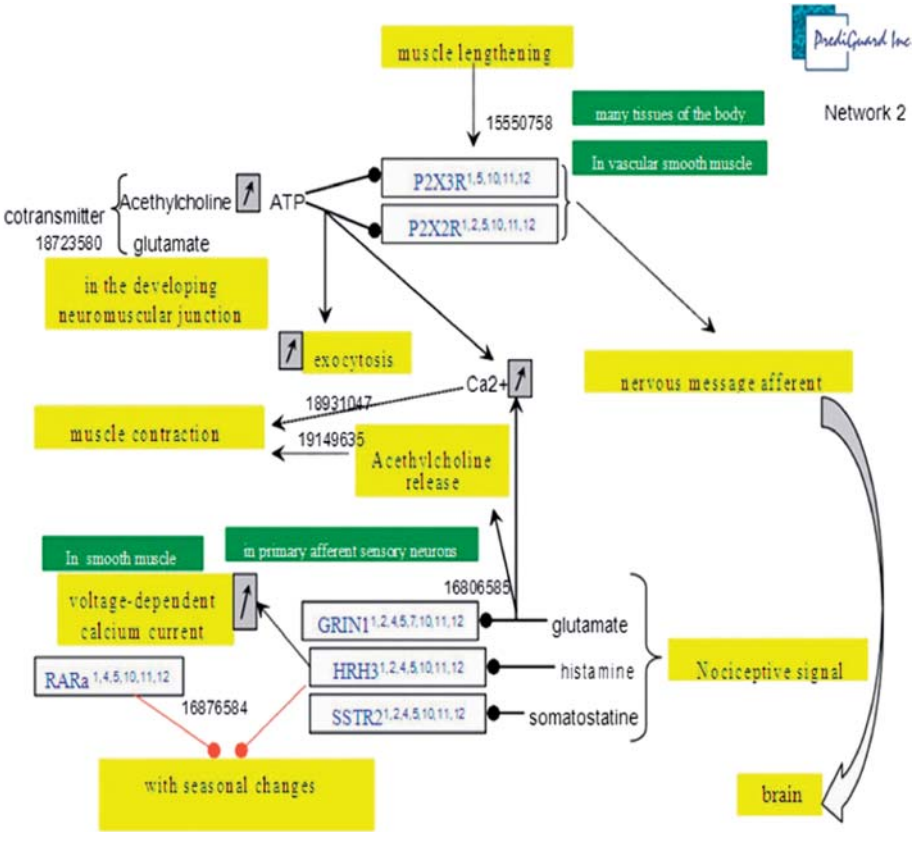
*** REDUSTIM : results on 12 individuals**
PLACEBO : results on 10 individuals

The comparative results of Redustim vs. Placebo with respect to ASAT transaminases are significant to risk a = 0.12.

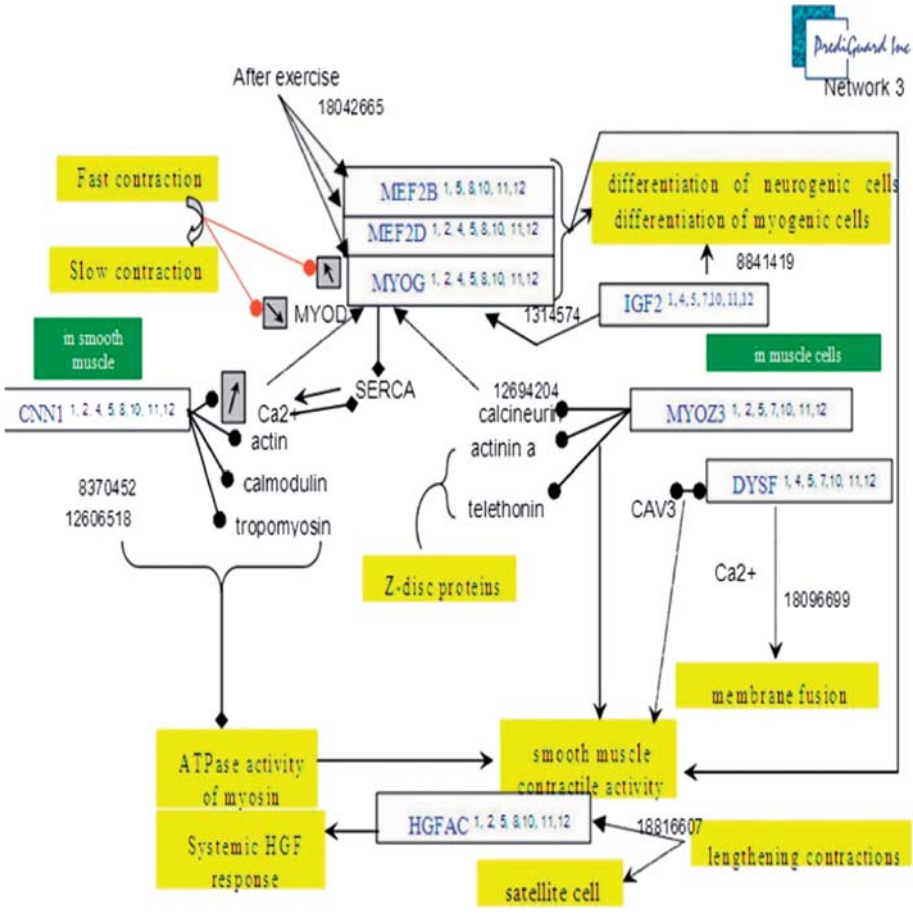
Annex 9



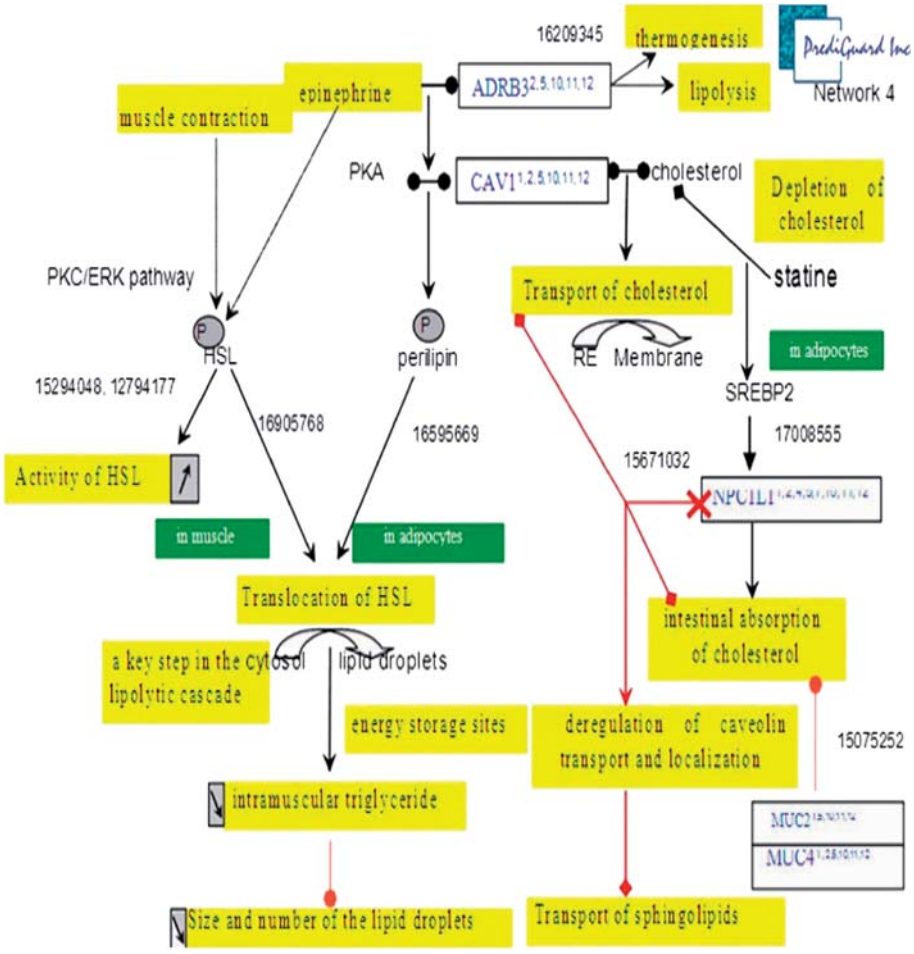
Annex 10



Annex 11



Annex 12



Annex 13