

Double-blind RCT of the LifeWave X39 Patch to determine GHK-Cu Production Levels

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Abstract

Double-blind RCT of the LifeWave X39 Patch to determine GHK-Cu Production Levels Connor, C., Connor, M., Yue, D., Eickhoff, J., Wagner, S., Perry, M., Chang, A.

Purpose

To determine if the LifeWave X39 non-transdermal patch would show improved production of the tri-peptide GHK-Cu (glycine, histidine and lysine) over controls in double blind testing.

Materials

BD Vacutainer Safety Loc Blood Collection sets were used with Pre-attached holder sized 21GX0.75 or 23GX0.75 and placed in lavender top tubes. Kendro Sorvall Biofuge Centrifuge 75005184+ and AB Sciex API4000 Qtrap. Analysis software included: Qtrap Analyst software 1.6.2. and R software version 3.5.1.

Method

Sixty people age 40-80 were randomized into two groups of A and B. All participants wore A or B patches for a period of min 8 hours per day. Blood was drawn into lavender top tubes on day 1, 2 and 7 with blood collection sets and spun in Kendro Sorvall centrifuge for 10 minutes at 1300 rcf. The plasma was placed in cryo tubes and flash frozen using dry ice then shipped to the laboratory for analysis. The filtrate was concentrated by speed-vac and reconstituted with de-ionized water to 50ul and analyzed with AB Sciex API4000 Qtrap. The data was analyzed with Analyst software 1.6.2. Results were then sent for statistical analysis using a Wilcoxon signed rank test. All reported p-values are two-sided and $p < 0.05$ was used to define statistical significance. Statistical analyses were conducted with R software version 3.5.1. Blind was broken after the statistical analysis was completed.

Results

A significant increase in GHK-CU concentration in the blood of the active group was seen in the p-value for comparing changes from Day 1 to Day 2, Day 1 to Day 7 and Day 2 to Day 7 between Group A vs. Group B in GHK-Cu Concentration (ng/ml) at $p < 0.035$ and in Total GHK-Cu (ng) at $p < 0.03$.

Conclusion

This study explored the changes in amounts of GHK-CU present in the blood as a result of wearing the Lifewave X39 patch for 1 week in individuals age 40 to 80. A significant increase in GHK-CU concentration in the blood of the active group was seen in the p-value for comparing changes from Day 1 to Day 2, Day 1 to Day 7 and Day 2 to Day 7 between Group A vs. Group B in GHK-Cu Concentration (ng/ml) at $p < 0.035$ and in Total GHK-Cu (ng) at $p < 0.03$.

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Introduction

This study explores the impact of wearing the Lifewave X39 patch over the period of one week on levels of GHK-Cu levels in the blood in a double-blind randomized controlled trial. Blood samples were taken at baseline, 24 hours and at 7 days of wearing the patch. A sample of convenience of 60 subjects made up of both men and women aged 40-81 were selected to participate in this study. Participants were randomized into Group A or Group B by computer.

Background

The Lifewave X39 patch uses phototherapy to stimulate a rebalancing of the body. Based on data from other studies, it was felt that a possible change in the copper tripeptide GHK- Cu might be a factor in the effects produced by the patch. As a follow on to prior studies it was determined that a double blind study was appropriate. The tripeptide has been demonstrated to improve tissue remodeling. “It increases keratinocyte proliferation and normal collagen synthesis, improves skin thickness, skin elasticity and firmness, improves wrinkles, photodamage and uneven pigmentation, improves skin clarity, and tightens protective barrier proteins.” (DeHaven, C., 2014) Research has identified that the peptide is used to signal the beginning of the natural repair process.

The Tripeptide

“Copper tripeptide-1(GHK-Cu) is a small protein composed of the three amino acids (protein building blocks) glycine, histidine, and lysine combined in a specific geometric configuration with the physiologically beneficial mineral (copper)” (DeHaven, C., 2014). This tripeptide was first isolated from human plasma albumin in 1973 by Dr. Loren Pickart.

Additional research has established the strong affinity the GHK peptide has for copper, and exists in two forms, as this was not covered in the initial experiment. These two forms are GHK and GHK-Cu. It is also important to mention that none of the research around GHK has ever found it to cause an issue. (DeHaven, C., 2014)

Non-transdermal Patch

All X39 patches are sealed so that none of the substances in the patch actually penetrate the skin. This allows for consistent patch promotion of the light flow throughout the time the patch is worn. Patches are designed to reflect wavelengths of light in the infrared, near infrared, and visible light bands. This patch uses the same adhesives as band-aids as this limits the level of irritation which might be developed through consistent daily use of the patch.

Phototherapy

Phototherapy in various forms has been used for over 100 years. In that time there has been little evidence of negative side effects. This suggests that this is a relatively untapped option for healing with relatively few risks.

Procedure

Once human research studies ethics board approval was received (NFFE 01-16-20-01) recruitment was begun. Flyers advertising for interested research participants were posted at various local sites. Participants would call into the main study phone number and were assessed for inclusion and exclusion criterion. If appropriate they were scheduled for consenting. At the time of arrival at the study site, each participant was consented and then randomized into group A or B. Individual participants were then taken into the exam room and a blood sample was taken at baseline, 24 hours and 7 days of patch placement. For convenience, participants were asked to use what is a recognized meridian point GV14, for the patch placement. BD Vacutainer

Safety Loc Blood Collection sets were used with Pre-attached holder sized 21GX0.75 or 23GX0.75 and placed in lavender top tubes. Each blood sample was then placed in the Kendro Sorvall Biofuge centrifuge 75005184+ HERAEUS 7591 with a 4000 RPM rotor, spun for 10 minutes at 1300 rcf to separate the plasma, which was then placed in the cryo tubes, and then flash frozen using a medical freezer. Samples were then placed in 2" thick polystyrene containers, wrapped in thermal box liners and placed in double walled boxes for overnight shipping. Samples were sent to HT-Labs a division of AxisPharm in San Diego, CA.

Analysis of Blood Samples

The blood samples were processed according to the original thesis of Dr. Pickard. The filtrate was concentrated by speed-vac and reconstituted with de-ionized water to 50ul and analyzed with AB Sciex API4000 Qtrap. The data was analyzed with Analyst software 1.6.2.

Statistical Analysis

Absolute changes in GHK and GHK-CU levels from baseline to the 24 hours and day 7 assessments were summarized in terms of means, standard deviations, medians and ranges. Changes from baseline to the 24 hours and day 7 assessments were evaluated using a nonparametric Wilcoxon signed rank test. All reported P-values are two-sided and $P < 0.05$ was used to define statistical significance. Statistical analyses were conducted using R software (version 3.5.1; <http://www.r-project.org/>). Once the statistical analysis was complete, the blind was broken.

Results

A sample of convenience of 60 individuals were randomized into two groups (A and B) with an age range of 41 - 80. Significant results of the Lifewave X39 patch testing are as follows:

Table 1: A significant increase in GHK-Cu concentration in the blood of the active group was seen in the p-value for comparing changes from Day 1 to Day 2, Day 1 to Day 7 and Day 2 to Day 7 between Group A vs. Group B in GHK-Cu Concentration (ng/ml) at $p < 0.035$ and in Total GHK-Cu (ng) at $p < 0.03$.

GHK-Cu Concentration (ng/ml)	Day 1 to Day 2	0.3465
	Day 2 to Day 7	0.035
Total GHK-Cu (ng)	Day 1 to Day 2	0.237
	Day 2 to Day 7	0.03

Discussion

This was a randomized double blind trial which used a sample of convenience recruited from the general population of the greater Tucson, AZ area. Individuals were age 40 - 81. It should be noted that this trial was interrupted by the COVID SARS-2 pandemic in March of 2020 and resumed in Aug of 2020. At that time special procedures were put in place to be sure of the safety and health of all participants. This included separation of times for scheduled blood draws, cleaning procedures between each participant. UV-C wand of all hard surfaces, Clorox wipe of draw chair, changes in gloves and gowns for all study team members and the wearing of masks for both participants and study team members were done. Study team members were tested weekly to confirm no contagion. No study participant developed COVID SARS-2 through participation in this study process. This study confirmed that there was a significant change in the levels of GHK-Cu in 7 days in both concentration and total amount. This data confirms data from earlier studies (Connor et al, 2019, Connor et al, 2019 (2) and Connor et al, 2021 pending). The repeated trials data supports promotion of positive benefits to the body through increased production of GHK-Cu.

Conclusion

This study explored the changes in amounts of GHK-Cu present in the blood as a result of wearing the Lifewave X39 patch for 1 week. A significant increase in GHK-Cu concentration in the blood of the active group was seen in the p-value for comparing changes from Day 1 to Day 2, Day 1 to Day 7 and Day 2 to Day 7 between Group A vs. Group B in GHK-Cu Concentration (ng/ml) at $p < 0.035$ and in Total GHK-Cu (ng) at $p < 0.03$.

References

- Becker, R., Selden, G., "The Body Electric", William Morrow Pub., New York, NY, 1985.
- Connor, M., Connor, C., Gombosuran, N., Eickhoff, J., Peugh, L., "LifeWave X39 Pilot Demonstrates Light Triggered Changes," International Journal of Healing and Careing, May 3, 2020. www.ijhc.org
- Connor, C., Connor, M., Yue, D., Chang, C., Eickhoff, J., Wagner, S., Chang, A., " Changes in Tripeptides Produced By the LifeWave X39 Patch" International Journal of Healing and Careing, May 3, 2020. www.ijhc.org
- Connor, M., Connor, C., Gombosuran, N., Eickhoff, J., Peugh, L. "Phototherapy Induced Metabolism Change Produced by the LifeWave X39 Non-transdermal Patch" Aug 2020, submitted and undergoing journal review.
- Deadman, P., Al-Khafaji, M., Baker, K., (2001) A Manual of Acupuncture. Eastland Press. 1240 Activity Dr., #D Vista, CA, 92083.
- DeHaven, C., (2014) Copper Tripeptide-1. Science of Skincare.
- Geo Peptides Staff. (2015) What are Copper Peptides? Retrieved August 5, 2018. <https://www.geopeptides.com/copperpep.html>
- Kakimoto, C., (2017) What is phototherapy, and how does it work? <https://www.dermatologistoncall.com/blog/what-is-phototherapy-and-how-does-it-work/>
- Pickart, L., Vasquez-Soltero, J., Margolina, A. (2014)GHK and DNA: resetting the human genome to health. BioMed Research International, vol. 2014,Article ID 151479, 10 pages.
- Pickart, L., Vasquez-Soltero, J., Margolina, A. (2015) GHK Peptide as a Natural Modulator of Multiple Cellular Pathways in Skin Regeneration. Hindawi Publishing Corporation BioMed Research International Volume 2015, Article ID 648108, 7 pages <http://dx.doi.org/10.1155/2015/648108>.