



Invitrx Therapeutics' Second Clinical Trial Report
ReLuma Anti-aging Serum
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Preface:

This is a summary of our second ReLuma clinical trial. The trial has reached the six month mark of a yearlong study. It is unpublished at this time and may be published in the future. This is an ongoing clinical trial with ReLuma Anti-aging Serum.

It is important to understand the purpose of the second trial. The first trial was simply designed to test the formulation for effectiveness, patient tolerability and acceptance. With the second clinical trial, there are more participants and an extended study length. In addition, photograph imaging was performed with the VISIA system every 90 days measuring particularly facial wrinkles. Participants were also asked to participate in surveys every 90 days to track their progress.

Introduction:

ReLuma anti-aging serum is formulated with a patent pending blend of Induced Pluripotent Stem Cells (IPS), Dermal Fibroblast, and Mesenchymal Stem Cell Conditioned Media with over 380 different growth factors, cytokines, and matrix proteins. These growth factors include TGF- β (1-3) [Transforming growth factor beta], PDGF [Platelet derived growth factor], GM-CSF [Granulocyte-macrophage colony-stimulating factor], and Interleukins (IL3, IL6-8) which are found in natural human skin. The growth factors, cytokines, and matrix proteins aid in the healing of the skin, reduces fine lines and wrinkles, improve cell turnover rate, promote cell proliferation of dermal cells, and increases collagen and elastin production to help improve skin thickness and texture.

The application of ReLuma, which contains multiple growth factors and proteins results in a more effective system for stimulating skin rejuvenation and regeneration. ReLuma's combined delivery of multiple, natural adult human growth factors has the ability to stimulate fibroblast production of collagen, stimulate keratinocyte and fibroblast proliferation, enhance blood vessel formation, and work as a potent anti-inflammatory agent in skin. These processes may then function to increase skin firmness and elasticity, reduce the appearance of fine lines and wrinkles, increase skin miniaturization and vibrancy, develop a smoother, silkier texture, even out skin colors and tones, and may result in thicker, younger looking skin.

Methods and Materials:

22 participants made up of 19 women and 3 men with ages ranging 36-76 with an average age of 49, used ReLuma twice a day for 6 months/180 days. Baseline pictures and self skin evaluations were taken at the start of the study. Participants' wrinkles were measured using the VISIA system. In addition, participants gave their responses to a comprehensive questionnaire. Participants returned for self evaluations and pictures at 90 day intervals. Images taken by the VISIA system, consisted solely of the left side of the participants face.

The VISIA System for complexion analysis is a camera unit which sends the high-quality photographs to a high speed computer. The computer calculates both the standard and UV photos by means of software analysis. The results of complexion analyses are a great tool for skin care consultants for anti-aging treatment planning and monitoring its progress. VISIA provides a wide array of functions including: skin & teintanalysis, measurement of pore depth, individual analysis of the skin condition, measurement of wrinkles, analysis of pigment disturbances, representation of UV damages, porphyrine & bacteria analysis of the facial skin, graphic evaluation of individual results, individual anti-aging treatment planning, and monitoring & progress control of therapies and cosmetic face treatments. Importantly, the system captures digital photos of the face and measures wrinkles, evenness, pores and pigmentation. An individual's skin features are graded relative to others of the same sex, age, and ethnicity.

The results of the image session include a number of factors which influence the actual scores generated by the VISIA complexion analysis algorithms, including the condition of the skin (cleaned vs. fresh make-up, old make-up, time of day), head registration within the booth, facial expression (particularly for wrinkles), stray hairs, glare areas resulting from oily skin, etc. Note that the percentile scores were generated for subjects with cleaned skin prior to their imaging session, so results may vary if make-up is NOT removed prior to a patient's VISIA session. The Procter & Gamble complexion analysis software used in VISIA was developed in the late 1990s and has undergone extensive lab and field-testing. The VISIA complexion analysis algorithms themselves are supported by an extensive set of research papers describing the analysis techniques and results across various skin types.

Results:

In general using the VISIA system, participants saw an average 5.4% increase in how their skin's wrinkles ranked amongst their age group after **90 days**.

In addition, there was an average of 12.3% increase in how their skin's wrinkles ranked amongst their age group after **180 days**.

Discussion:

The progression was not consistent due to the fact some had make up on their baseline photos which resulted in a decline in ranking on their consecutive photo. Our protocol asked that participants use ReLuma twice a day, morning and night, however some participants decreased use when they developed small condones. ReLuma didn't work on all participants, though it improved their skin texture, the amount of wrinkles stay relatively consistent as their rank among their age group stayed relatively the same throughout the 6 months. We will continue to monitor their wrinkles in consecutive VISIA imaging photos. There have been drastic improvements with a continual increase in ranking; however it is too early to tell whether or not participants will plateau once a certain time period has been reached. We will continue to observe their progression and come out with a final clinical trial report at the end of the yearlong study.

It seems important to do a follow up study after the yearlong study to see if participants have maintained their rank with a discontinued use of ReLuma. Whether their skin regresses back to their original condition or it is maintained without its use.

Conclusion:

Average progression of rank amongst age group is approximately 5.4% after 90 days and 12.3% after 180 days. ReLuma helps improve the appearance of wrinkles.

Special thanks to Ergonique for the use of their facility and VISIA system.
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Charts and Images:



