Title of research study: Comparison of the cosmetic effects of Bakuchiol and Retinol

Investigator: Raja Sivamani, MD

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are between the ages of 30 and 55. We hope to learn more about whether a topical cosmetic botanical agent can reduce the appearance of photodamage and wrinkles compared to a standard Retinol treatment.

What should I know about a research study?

(Experimental Subject's Bill of Rights)

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
  - Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study.
  - Medical treatment, if any, that is available for complications.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document**.**
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Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 916-734-1509 (Iryna Rybak).

For non-emergency issues you can call the UCDMC Hospital Operator at 916-734-2011, tell the Operator you are participating in a research study and you wish to talk to dermatology resident on-call. In the case of an emergency, dial 911 from any phone.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). Information to help you understand research is on-line at http://www.research.ucdavis.edu/policiescompliance/irb-

admin/.You may talk to an IRB staff member at (916) 703-9151, IRBAdmin@ucdmc.ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

There are several purposes of this study:

1) We want to see whether there is any difference in skin appearance or texture over a 12 week period with a botanical cosmetic agent.
2) We want to compare this to Retinol treatment.

How long will the research last?

This research study will be conducted over 1 year. However, your physical participation in the study is no more than four (4) visits of approximately 1 hour per visit. Your total participation in the study is approximately 12 weeks.

How many people will be studied?

We expect about 50 people will be in this research study.

What happens if I say yes, I want to be in this research?

If you decide to participate in this study, you will be asked to attend no more than four study visits. Each visit will last approximately one hour. Visits will take place at the UC Davis Department of Dermatology at 3301 C Street, Suite 1400, Sacramento, CA 95816 or in the UC Davis Dermatology Research Labs on the main campus at UC Davis. You will be mainly interacting with the staff members of our research team throughout the entire study.

You will be asked to refrain from applying any products containing salicyclic acid, beta hydroxyl acids or vitamins A, C or E to your face two weeks prior to your first study visit and for the duration of the study. You will asked to avoid applying retinoids for 30 days prior to the study start and for the duration of the study. It is recommended that you use sunscreen with SPF 30 during this study. You will be provided with sunscreen during the study. .

You will be assigned by chance (like flipping a coin) to 1 of the following study groups:

- Bakuchiol
- Retinol

You have an equal chance of being in either of the study groups. Neither you nor the study doctor or study staff will be able to pick which study group you are in. Neither you nor the study doctor will know which study group you are in. During the study your tubes will be weighed and you will be provided with new tubes at each visit. Sunscreen will be provided during the study and weighed at each visit.

Visit 1: During the first study visit, if you are female, you will have a research related urine pregnancy test, except for females who have had hysterectomy. If your pregnancy test is positive, you will not be allowed to continue in the study.

- Study team will take facial photographs during this visit
- You will be randomized to a treatment of Bakuchiol or Retinol
- You will be given a study agent log and your assigned topical agent will be weighed prior to being given to you
- The study team will perform assessments of your skin
- You will apply your assigned treatment during the study visit

Visit 2 (week 4**):** We will ask you not to apply topical agent to your face the day of the study visit. We ask you to bring your study agent to this visit:

- Study team will take facial photographs during this visit
- Study team will perform a pregnancy test, except for females who have had hysterectomy.
- Your previous log will be collected by the study team and you will be provided with a new one
- Your topical agent will be weighed
- Staff will perform assessments of your skin

Visit 3 (week 8): We will ask you not to apply topical agent to your face the day of the study visit. We ask you to bring your study agent to this visit:

- Study team will take facial photographs during this visit
- Study team will perform a research related pregnancy test, except for females who have had hysterectomy.
- Your previous log will be collected by the study team and you will be provided with a new one
- Your topical agent will be weighed
- Staff will perform assessments of your skin

Visit 4 (week 12) We will ask you not to apply topical agent to your face the day of the study visit. We ask you to bring your study agent to this visit:

- Study team will take facial photographs during this visit
- Your study log will be collected and your topical agent will be returned and weighed
- Staff will perform assessments of your skin

After this visit, this will conclude your participation in the study**.**

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

1. NOT apply any other retinoid based cream for the duration of the study
2. Not apply products or your study cream on the day of the visit
3. Come for up to four study sessions, each lasting approximately one hour
4. Use the study agents as advised
5. Inform the research team if you experience any discomfort at any time during the study
6. Please let the study team know if you think you might be pregnant

What happens if I do not want to be in this research?

You may decide not to take part in the research study and it will not be held against you.

What happens if I say yes, but I change my mind later?

You can leave the research study at any time and it will not be held against you.

Tell the investigator if you are thinking about stopping or decide to stop. There are no risks from stopping the study early and this will not be held against you. If you develop side effects, he/she may need to stop the study early.

If you stop being in the research study, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me?

There is a low chance for any psychological, social or legal injury from the participation.

Physical risks may include:

- From the retinoid based topical agent (if you are in this group):
    - Common: redness, dry skin, peeling, irritation
- From the Bakuchiol (if you are in this group): Usually this is well tolerated, however side

effects could include:

- Mild itching
- Redness with sensitive skin

There may also be risks to your privacy. The researchers will store study records and other information about you in a secure location and will grant access only to those with a need to know. However, just like with other personal information kept by your health care providers, your banks, and others, even these safeguards cannot guarantee absolute protection of the data. If private information gets into the wrong hands, it can cause harm. Although rare, there are reported cases of breaches that have resulted in discrimination in insurance or employment.

You should not be or become pregnant while in this research study. If you are planning to become pregnant, please discuss this with the study doctor. It is not recommended to breastfeed whilst using these topical agents.

Will being in this study help me in any way?

Your participation may add to the general scientific knowledge that may lead to benefit in the future for others.

What happens to the information collected for the research?

All of your data will be entered into data sheets as codes and a separate password protected file will contain the key for these codes. All of the files will be saved on computers that will be within locked rooms. The research team will follow the UC Davis Institutional Policy for data security to ensure that all of your collected data is protected.

The photographs that are taken with the photography machine by the research team will also be saved in secure data folder without any other identifying information.

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

The IRB will be granted direct access to your research records to oversee the study. We may publish the results of this research. However, we will keep your name and other identifying information confidential. Your photographs will not be used in any publications unless we obtain a separate signed publication consent from you to use your images.

If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record.

If that happens, your research records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/compliance/pdf/notice.pdf) and in an attached document.

During your participation in this research, data will be collected about you. The de-identified data will become the property of the University of California. The data may be used in this research, may be used in other research, and may be shared with other organizations. The data could lead to discoveries or inventions that may be of value to the University of California or to other organizations. Under state law you do not have any right to money or other compensation stemming from products that may be developed from the specimens.

Description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/compliance/pdf/notice.pdf) and in an attached document.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal includes failure to comply to study instructions, pregnancy, development of adverse side effects, and if there is a significant protocol deviation.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

There is no charge for you to participate in this study. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor/department.

You or your health plan will be billed for the costs of routine medical care you receive during the study. These costs may include operating room fees, pharmacy charges, treatments, hospitalization, scans, etc. You will be expected to pay for the usual deductibles and co-payments, and for any routine care that is not covered. Only the costs of research or experimental procedures will be paid by the study**.**

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may call the IRB Administration at (916) 703-9151 or email at IRBAdmin@ucdmc.ucdavis.edu.

If you agree to take part in this research study, we will compensate you for your time and effort (please see below). Payment will be provided by check which will be mailed to subjects after completion of visit 4. If you do not complete the study, payment will be based on the number of completed visits as listed below. You may be asked for your social security number for payment purposes. It will not be used for any other purpose without your permission.

The results of this study, including specimens collected, may have commercial value to the sponsors, UC Davis, and/or the researchers. You will have no legal or financial interest in any commercial development resulting from the research or from the information or materials collected.

Visit	**Compensation**
Visit 1:	$20
Visit 2:	$20
Visit 3:	$30
Visit 4:	$30
Total: (checks mailed after completion of visit 4)	$100

Are there other research opportunities?

If you are interested in being contacted for future research, please provide your phone number and/or email. This is completely optional.

_____(Initials) Yes, I am willing to be contacted for future research opportunities. My phone number and/or email is: _____.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	