

# A study to evaluate a facial cream containing 0.5% bakuchiol on subjects with acne

<b>Submission date</b> 10/07/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/09/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/03/2021	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Acne is an extremely common skin disease that is found most typically in adolescence and young adulthood. It causes spots, oily skin and sometimes skin that's hot or painful to touch. The aim of this study is to evaluate the effectiveness and acceptance of UP256 cream, 0.5% in the treatment of acne.

### Who can participate?

People aged 12-30 with mild to moderate acne

### What does the study involve?

Participants are required to follow instructions from the investigator and apply a cream to their face twice a day. The length of the study is 16 weeks and consists of a screening visit, baseline visit (week 0), and treatment visits at weeks 1, 2, 4, 6, 8, 10 and 12. The screening and baseline visit assessment will include an acne lesion count and the first application of the cream by the participant. Treatment visits will also include an evaluation of the response to treatment, a patient questionnaire, acne lesion count, safety assessment, collection of study medication and reporting of adverse events.

### What are the possible benefits and risks of participating?

The study does not promise any benefit but a possible benefit could be a clearer complexion. The most common foreseeable adverse events include erythema (redness), irritation and peeling of the skin due to a known mild irritation quality of the topical antibiotics. A risk of participating in the study is that participants are not able to use other acne medication and their condition may worsen.

### Where is the study run from?

SUNY Downstate Medical Center (USA)

### When is the study starting and how long is it expected to run for?

March 2009 to June 2010

Who is funding the study?  
Unigen Inc. (USA)

Who is the main contact?  
Lidia Alfaro Brownell  
lbrownell@unigen.net

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Lidia Alfaro Brownell

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## Additional identifiers

**Protocol serial number**  
UN2008-256-01

## Study information

**Scientific Title**  
A pilot, open-label study to evaluate the antimicrobial and anti-inflammatory properties of UP256 cream

**Study objectives**  
0.5% bakuchiol cream reduces total acne lesions when applied twice a day for a period of 12 weeks.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Approved 06/04/2009, SUNY Downstate Medical Center Institutional Review Board (450 Clarkson Avenue Brooklyn, NY 11203, USA; +1 (0)718 270 2680; irb@downstate.edu), ref: 09-008

**Study design**

Single-center open-label interventional study

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Acne and hyperpigmentation

### **Interventions**

A cream containing 0.5% bakuchiol was applied to the face twice a day for a period of 12 weeks. The study was open-label and no control group or placebo was used. Participants that met the inclusion criteria were enrolled and assigned to the study product. The length of the study is 16 weeks and consists of a screening visit, baseline visit (week 0), and treatment visits at weeks 1, 2, 4, 6, 8, 10 and 12.

### **Intervention Type**

Other

### **Primary outcome(s)**

1. Acne inflammatory lesions and non-inflammatory lesions measured using lesion count at baseline and weeks 4, 8, and 12
2. Post-inflammatory hyperpigmentation caused by acne measured using physician assessment method at baseline and weeks 4, 8, and 12

### **Key secondary outcome(s)**

Safety and tolerability of the cream measured by investigator assessment of erythema (redness), dryness, peeling and oiliness at baseline and weeks 1, 2, 4, 6, 8, 10 and 12

### **Completion date**

30/06/2010

## **Eligibility**

### **Key inclusion criteria**

1. Male or female
2. Moderate to mild acne
3. Age 12-30
4. Fitzpatrick Skin Type III and higher

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

**Sex**

All

**Total final enrolment**

17

**Key exclusion criteria**

1. Not healthy
2. Severe acne
3. Recent use of acne treatment

**Date of first enrolment**

17/04/2009

**Date of final enrolment**

15/11/2009

**Locations****Countries of recruitment**

United States of America

**Study participating centre****SUNY Downstate Medical Center**

450 Clarkson Avenue

Brooklyn, New York

United States of America

11203-2098

**Sponsor information****Organisation**

Unigen Inc.

**Funder(s)****Funder type**

Industry

**Funder Name**

Unigen Inc.

# Results and Publications

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date. Currently data to be used for publication is saved as the analyzed file in an Excel format on a CD, the file is de-identified as per HIPAA Guidelines and stored in a limited access area at Unigen Inc.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2021	09/03/2021	Yes	No
<a href="#">Basic results</a>		11/09/2020	08/10/2020	No	No