ISRCTN13992386 https://doi.org/10.1186/ISRCTN13992386

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

Submission date
10/07/2020

Recruitment status
No longer recruiting

Registration date
11/09/2020

Overall study status
Completed

Last Edited
09/03/2021

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

ORCID ID
https://orcid.org/0000-0002-5328-0152

Contact details
2121 South State Street Suite 400
Tacoma
United States of America
98405
+1 (0)253 274 7166
lbrownell@unigen.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

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?
Results article	results	01/03/2021	09/03/2021	Yes	No
Basic results		11/09/2020	08/10/2020	No	No