

# Efficacy of a spray formulation in acne of the chest and back

<b>Submission date</b> 02/05/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 05/05/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 05/05/2016	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Acne is a common skin condition which causes spots to develop on the skin, usually the face, chest and back. Even cases of mild acne can be distressing, as not only can it make people feel self-conscious, it can be painful. The majority of treatments for acne involve applying medications directly to the skin (topical medication), such as creams, gels and lotions. These products can contain a wide range of different chemicals, including retinoids (vitamin A by-products that help to remove dead skin cells from the surface of skin), antibiotics (which kill bacteria on the skin that can cause infections leading to spots) and keratolytic substances (peeling agents). When acne affects the chest or back, it can be difficult to apply topical medications in the form of creams, gels and lotions as these areas can be hard to reach. Sprays are therefore considered to be a far more convenient treatment option, as they are able to reach where the sufferer otherwise would not be able to. The aim of this study is to compare three different acne spray formulations, in order to find out if a spray containing retanoids, antibiotics and keratolytic substances is more effective than sprays containing keratolytic substances alone.

### Who can participate?

Adults with mild to moderate acne on the back and chest.

### What does the study involve?

Participants are randomly allocated to receive one of three products. The first product is a new spray which contains retinol and hydroxypinacolone retinoate (vitamin A by-products), an antibacterial product, salicylic acid (a plant hormone commonly used to treat common skin and foot warts) and, vitamin E. The second and third products both contain different keratolytic substances (peeling agents that help to soften and shed the outer layer of skin). All products are applied twice a day for six weeks using four to five sprays on the affected area of skin. At the start of the study and after six weeks, participants in all groups have their acne examined to find out if there has been any improvement. Participant are also interviewed after six weeks in order to find out how their skin has reacted to the spray that they used.

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

Participants may benefit from an improvement to their acne as a result of using the treatment

sprays. There are no notable risks involved with taking part in the study, although there is a chance than the product used may not be effective or cause skin irritation.

Where is the study run from?

Clinica di Dermatologia Seconda Università Napoli (Italy)

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

December 2014 to February 2016

Who is funding the study?

Difa Cooper (Italy)

Who is the main contact?

Dr Massimo Milani

## Contact information

### Type(s)

Public

### Contact name

Dr Massimo Milani

### Contact details

Difa Cooper

Via Milano 160

Caronno Pertusella

Italy

21042

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

BR2015/1

## Study information

### Scientific Title

Efficacy and local tolerability of different spray products in the treatment of mild to moderate acne of the back and chest: A controlled, three-arm, assessor-blinded prospective trial

### Study objectives

The aim of this study is to evaluate whether a spray containing retinoids, antibacterial, emollient and keratolytic substances is more effective than other two products containing containing keratolytic and emollient compounds only at treating moderate acne of the chest and back.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Policlinico Federico II Naples, 10/01/2015

**Study design**

Prospective observer-masked three arm randomised parallel trial

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

No specific participant information sheet available, please use the contact details below to request a further information.

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

Truncal acne vulgaris

**Interventions**

Participants are randomly allocated in a 1:1:1 ratio to receive one of three products.

Product 1: A new spray formulation containing 0.15% of two vitamin A derivatives (retinol and hydroxypinacolone retinoate) carried in a patented glycospheres system (RetinSphere®), an antimicrobial peptide (BIOPEP.15), salicylic acid and, vitamin E (BR).

Product 2: A spray formulation containing triethyl citrate and ethyl linoleate, GT-peptide-10, salicylic acid 0,5% and Zinc Lattate.

Product 3: A spray formulation containing betaine, glycine and salicylic acid 2% (SP).

All products are to be applied twice daily (one application in the morning and one application in the evening) for 6 consecutive weeks. The total amount of product is 4/5 puffs per application (a total of 1.2/1.5 ml), in order to cover chest and back areas.

All participants are followed up at six weeks.

**Intervention Type**

Drug

**Phase**

Phase III/IV

**Drug/device/biological/vaccine name(s)**

1. Bioretix ultra spray 2. Aknicare CB 3. Salipil spray

**Primary outcome measure**

Clinical evolution of acne lesions is measured using the Global Acne Grading System (GAGS) at baseline and 6 weeks.

**Secondary outcome measures**

Skin tolerability is measured by evaluating skin irritation (erythema and burning) and skin xerosis using a quantitative score from 0(no symptom) to 3(relevant symptom) at 6 weeks.

**Overall study start date**

01/12/2014

**Completion date**

01/02/2016

**Eligibility****Key inclusion criteria**

1. Aged 18 years and over
2. Presence of mild to moderate acne involving back and chest regions (truncal acne)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

75 (a total of 25 subjects per treatments arm)

**Key exclusion criteria**

1. Severe forms of acne requiring systemic treatments
2. Other severe skin conditions
3. Use of topical acne medications such as tretinoin, benzoyl peroxide or topical antibiotics within 2 weeks
4. Use of oral antibiotics within 30 days
5. Use of systemic corticosteroids within 4 weeks
6. Body Mass Index >30

**Date of first enrolment**

02/02/2015

**Date of final enrolment**

01/12/2016

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre**

Clinica di Dermatologia Seconda Università Napoli

Via Pansini

Naples

Italy

0182

## **Sponsor information**

**Organisation**

Difa Cooper

**Sponsor details**

Via Milano 160

Caronno Pertusella

Italy

21042

**Sponsor type**

Industry

**ROR**

<https://ror.org/044sr7e96>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Difa Cooper

# Results and Publications

## Publication and dissemination plan

Planned publication in a peer reviewed journal.

## Intention to publish date

30/09/2016

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Stored in repository