# An observer blind, parallel group, randomised multicentre study to compare the safety and efficacy of a new formulation of topical clindamycin phosphate in patients with mild to moderate acne

Submission date	Recruitment status	Prospectively registered		
09/09/2005	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/10/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
17/09/2009	Skin and Connective Tissue Diseases			

# Plain English summary of protocol

Not provided at time of registration

#### Contact information

## Type(s)

Scientific

#### Contact name

Prof WJ Cunliffe

#### Contact details

Department of Dermatology Leeds General Infirmary Leeds United Kingdom LS1 3EX

### Additional identifiers

Protocol serial number ZCG/4/C

# Study information

#### Scientific Title

#### **Study objectives**

To ascertain the efficacy of a new formulation of topical clindamycin gel.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Multicentre randomised active controlled parallel group trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

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

Mild to moderate acne vulgaris.

#### **Interventions**

Zindaclin® 1% Gel (twice a day [bd] & once a day [od]) and Dalacin-T® Topical Lotion (bd).

#### Intervention Type

Drug

#### **Phase**

**Not Specified** 

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

Zindaclin® 1% Gel and Dalacin-T® Topical Lotion

#### Primary outcome(s)

The change in facial inflammatory lesion count from baseline visit to the end of treatment (week 16).

#### Key secondary outcome(s))

- 1. The change in acne grade (The Leeds Revised Acne Grading System, 1998) from the baseline visit to the end of treatment
- 2. The change in number of total comedones, open comedones, closed comedomes, pustules
- 3. Mean change in total lesion count
- 4. Patients global assessment
- 5. Investigators global assessment

#### Completion date

29/09/2000

# **Eligibility**

#### Key inclusion criteria

Consenting patients of either sex, between 12 and 40 years of age, with mild to moderate inflammatory acne with a grade ranging from 2.0 to 7.0 (The Leeds Revised Acne Grading System, 1998).

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Other

#### Sex

All

#### Key exclusion criteria

- 1. Patients with significant nodulocystic acne
- 2. Use of systemic topical antibiotics within 4 weeks prior to the start of treatment
- 3. Concomitant medication which may interfere with study evaluation

#### Date of first enrolment

19/07/1999

#### Date of final enrolment

29/09/2000

#### Locations

#### Countries of recruitment

United Kingdom

England

# Study participating centre Department of Dermatology

Leeds United Kingdom LS1 3EX

# Sponsor information

#### Organisation

ProStrakan Pharmaceuticals (UK)

#### **ROR**

https://ror.org/017hh7b56

# Funder(s)

#### Funder type

Industry

#### Funder Name

ProStrakan Pharmaceuticals (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2005		Yes	No