

A randomised, single centre, phase IV crossover study to assess the acceptability of once daily Zindaclin® used for one week compared to three other marketed topical antibiotics in patients with mild to moderate acne

Submission date 09/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 06/10/2005	Overall study status Completed	☐ Protocol
Last Edited 01/08/2012	Condition category Skin and Connective Tissue Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ZCG/38/C

Study information

Scientific Title

Study objectives

To assess the patient acceptability of Zindaclin® when compared to other marketed topical antibiotics.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised active controlled crossover group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mild to moderate acne vulgaris.

Interventions

1. Zindaclin® once daily
2. Benzamycin® twice daily
3. Zineryt® twice daily
4. Dalacin-T® Topical Lotion twice daily

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Zindaclin®, Benzamycin®, Zineryt®, Dalacin-T®

Primary outcome(s)

Patient Acceptability Questionnaire assessing the four study products.

Key secondary outcome(s)

1. A conjoint analysis assessment of product preferences
2. The level of product use

Completion date

09/10/2002

Eligibility

Key inclusion criteria

Male and female patients aged between 16 and 40 years with mild to moderate acne graded between 1.0 and 7.0 on the Leeds Revised Acne Grading System, 1998.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients with acne conglobata, acne fulminans, sandpaper acne, submarine comedonal acne or secondary acne were excluded
2. The use of topical or systemic antibiotics or topical antimicrobials within the previous week was disallowed

Date of first enrolment

20/02/2002

Date of final enrolment

09/10/2002

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Inveresk Research International

Tranent

United Kingdom

EH33 2NE

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	01/03/2006		Yes	No