

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 01/08/2012	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Patient Acceptability Questionnaire assessing the four study products.

Secondary outcome measures

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

Overall study start date

20/02/2002

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

Age group

Adult

Sex

Both

Target number of participants

65

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

Scotland

United Kingdom

Study participating centre
Inveresk Research International
Tranent
United Kingdom
EH33 2NE

Sponsor information

Organisation
ProStrakan Pharmaceuticals (UK)

Sponsor details
Buckholm Mill Brae
Galashiels
United Kingdom
TD1 2HB

Sponsor type
Industry

Website
<http://www.prostrakan.com>

ROR
<https://ror.org/017hh7b56>

Funder(s)

Funder type
Industry

Funder Name
ProStrakan Pharmaceuticals (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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