ISRCTN43187439 https://doi.org/10.1186/ISRCTN43187439

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	Recruitment status
09/09/2005	No longer recruiting
Registration date	**Overall study status**
06/10/2005	Completed
Last Edited	**Condition category**
01/08/2012	Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Inveresk Research International
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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