ISRCTN72179764 https://doi.org/10.1186/ISRCTN72179764

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 09/09/2005	**Recruitment status** No longer recruiting
Registration date 06/10/2005	**Overall study status** Completed
Last Edited 17/09/2009	**Condition category** 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
Prof WJ Cunliffe

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Multi-centre

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
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 measure

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

Secondary outcome measures
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

Overall study start date
19/07/1999

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

Age group
Other

Sex
Both

Target number of participants
270

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

England

United Kingdom

Study participating centre
Department of Dermatology
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
ProStrakan Pharmaceuticals (UK)

Sponsor details
Buckholm Mill Brae
Galashiels
United Kingdom
TD1 2HB

Sponsor type
Industry

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	01/09/2005		Yes	No