ISRCTN21526350 https://doi.org/10.1186/ISRCTN21526350

Identification of the most cost effective, microbiologically safe antimicrobial treatments for acne

Submission date	Recruitment status	[_] Prospectively registered
25/04/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2017	Skin and Connective Tissue Diseases	

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
HTA 94/48/03

Study information

Scientific Title
Identification of the most cost effective, microbiologically safe antimicrobial treatments for acne: a randomised controlled trial

Study objectives
The aims of this study are to assess the relative clinical efficacy of the currently available oral and topical antimicrobial therapies for acne vulgaris and to compare their potential to promote or prevent the emergence of antibiotic resistance in Propionibacterium acnes, the organism implicated in the development of inflamed lesions. At present selection of therapy for individual patients is largely random and there is no convincing evidence in the literature for the superiority of specific agents. There is a bias towards the use of more expensive drugs without adequate justification. Given the prevalence of acne and the long duration of the disease, there is much scope to reduce the cost of therapy without compromising therapeutic efficacy or safety. In order to achieve this a pharmaceutical industry-independent randomised controlled parallel group study in general practice is proposed.
As well as identifying the most active and cost effective therapies the study will also provide a detailed comparison of the clinical and microbiological safety profiles of the products tested.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Randomised controlled 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
Skin and connective tissue diseases: Skin and connective tissue diseases

Interventions
Interventions:
In this randomised, observer-masked trial, 649 community participants were allocated one of five antibacterial regimens. There were 649 participants in the main 5 treatment groups (+112

on 6 treatments discontinued early in the trial due to slow recruitment).
1. 500 mg oral oxytetracycline (non-proprietary) b.d. + topical vehicle control b.d.
2. 100 mg oral Minocin MR® (minocycline) o.d. + topical vehicle control b.d.
3. Topical Benzamycin® (3% erythromycin + 5% benzoyl peroxide) b.d. + oral placebo o.d.
4. Topical Stiemycin® (2% erythromycin) o.d. + topical Panoxyl® Aquagel (5% benzoyl peroxide) o.d. + oral placebo o.d.
5. Topical Panoxyl® Aquagel (5% benzoyl peroxide) b.d. + oral placebo o.d. (the active comparator group)

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
1. Proportion with at least moderate improvement in patient global self-assessment
2. Change in inflamed lesion count, both at 18 weeks from start of treatment

Secondary outcome measures
The Burke and Cunliffe grade, assessor global assessment of the participant, a new acne severity score (combined assessment of inflamed lesions, non-inflamed lesions & redness of face), the Short-Form 36 questionnaire, the Dermatology Life Quality Index, the Dermatology Quality of Life questionnaire, local irritation (assessed by both participant and assessor and indirectly by use of moisturisers), the proportion of participants for whom the worst aspect of their acne had improved, re-referral rates after treatment completion, other adverse events and drop out rates, bacterial skin colonisation (with propionibacteria resistant to erythromycin, clindamycin or the tetracyclines estimated at baseline and all subsequent on treatment visits using a semi-quantitative scoring method to derive data on both prevalence and population density).

Overall study start date
03/11/1997

Completion date
02/08/2001

Eligibility

Key inclusion criteria
Participants were 649 people aged 12-39 years, all with mild to moderate inflammatory acne of the face.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
649

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
03/11/1997

Date of final enrolment
02/08/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital
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Sponsor information

Organisation
Department of Health (UK)

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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	01/12/2004		Yes	No
Other publications	HTA monograph	01/01/2005		Yes	No