

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

Submission date

25/04/2003

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

25/04/2003

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

04/10/2017

Condition category

Skin and Connective Tissue Diseases

☐ 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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

University Hospital

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Department of Health (UK)

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

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