

FOCUS ON RESEARCH

NEWER APPROACHES TO EFFICACY TRIALS OF TOPICAL AGENTS IN PSORIASIS: A PILOT STUDY

Researchers

Ms Karen Waterston, a research nurse, was employed 50% of her time over a 12 month period.

Aim

Our aim was primarily methodological:

1. How well could we recruit patients from the community (as compared with secondary care).
2. Estimate the relative power of within versus between-person trials of topical agents for psoriasis.
3. Pilot a pragmatic design involving choice of therapy, if an initial therapy failed.

Project Outline/Methodology

We carried out a randomised control trial using agents currently available for the treatment of psoriasis. Our aims, as itemised above, were primarily methodological. Our design called for 60 patients, initially treated with two topical agents in a side by side comparison, with a decision at 8 weeks as to whether to change to a third treatment based on objective and subjective response (a vitamin D cream, an emollient and a tar preparation).

Key Results

48 (of a target of 60) individuals were recruited.

1. Recruitment via General Practitioners was poor but advertisements allowed selection of patients from the community.
2. The rating scale chosen, one that is commonly used in commercial studies, was less than adequate.
3. Within-person, as compared with between-person studies, are twice as powerful in terms of statistical power.
4. Even in this small pilot study, it was easily possible to demonstrate highly significant differences between the agents used, both for

the patient subjective scores and objective measures of disease activity.

5. There is some evidence that certain body sites respond differently.

Conclusions

Powerful studies of topical agents can be carried out on patients from the community using within person comparisons. Studies involving change of therapy, in an attempt to mirror every day clinical practice, are feasible.

What does this study add to the field?

Although within person studies have been carried out before, none have tried to formally assess their power in comparison with between person studies. The present study suggests that they are an alternative to large pharmaceutical funded "licence seeking studies".

Implications for Practice or Policy

A full study building on the present pilot study is required.

Where to next?

A definitive study of topical agents incorporating change of therapy and patient choice.

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