The University of Nottingham

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the BLISTER *study*

The Bullous Pemphigoid Steroids and Tetracyclines Study

The BLISTER study compared two medications for the treatment of a blistering skin condition called bullous pemphigoid. The study looked at how safe and effective the medications were. The data from the study has now been analysed and we are pleased to be able to share the results with you. We'd like to thank you for all your help with the study and hope you find the information in this newsletter useful.

What is Bullous Pemphigoid?

Bullous pemphigoid is a rare auto-immune condition that causes the immune system to mistakenly make antibodies against the skin. This causes large, itchy blisters to appear on the body, and if these blisters burst, secondary infection can occur.

How is it treated?

Oral steroids, such as prednisolone, are the standard treatment. They clear blisters quickly, and there is a lot of good evidence from clinical studies to support their use. Antibiotics are also sometimes used to treat bullous pemphigoid, but there has only been one very small clinical study looking at how well this treatment works.

Why conduct a study?

Oral steroids can cause fairly serious and long term side effects, so they are not an ideal treatment for bullous pemphigoid. Some may also find it difficult to taper the dose of steroids. We carried out this study to see how safe and effective an oral steroid medication (prednisolone) was compared to an antibiotic medication (doxycycline) for treating bullous pemphigoid.

We suspected doxycycline would not work as well as prednisolone, but thought that it would work reasonably well, and the trade-off would be that doxycycline would be far safer in the long term.

Who took part?

At 61 hospitals, 53 in the UK and 7 in Germany, people with bullous pemphigoid were invited to join the BLISTER study. Participants started treatment with either doxycycline or prednisolone. A total of 253 people decided to take part, of these, 132 participants began doxycycline treatment and 121 participants began prednisolone treatment.

NOTTINGHAM CLINICAL TRIAL UNIT

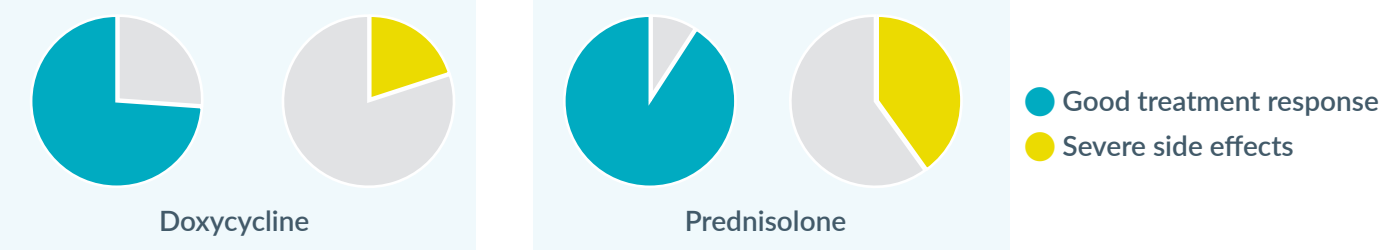
MRC Medical Research Council

UK Dermatology Clinical Trials Network

NHS National Institute for Health Research

What were the key findings of the study?

After 6 weeks of treatment, almost three-quarters (74%) of people in the doxycycline group had a good treatment response (3 or fewer blisters) compared with 91% in the prednisolone group. Over a year of treatment, 4 in 10 people experienced serious side effects who started on prednisolone compared to 2 in 10 who started on doxycyline. The results were about the same for people who had mild, moderate or severe bullous pemphigoid.



What does this mean?

Although more people starting on prednisolone had a good treatment response than those on doxycycline, they also experienced significantly more severe side effects. It should be kept in mind that although fewer participants starting on doxycycline had a good treatment response (compared to those starting on prednisone), many participants – nearly three quarters – did have a good response. Additionally, these participants did not experience as many severe, life threatening or fatal side effects. This study gives doctors and patients another option for bullous pemphigoid treatment. Doxycycline, although not quite so effective in the short term, is a significantly safer treatment in the long term.

Starting treatment with doxycycline is reasonably effective in the short-term and much safer than starting treatment with oral steroids in the long-term.

What will happen with the results?

We are working hard to ensure the results of the study are seen by both doctors and patients around the world. We have published the results of the study in The Lancet - one of the top medical journals - and also in a comprehensive NIHR report. These publications, as well as other information about the study, can be accessed via the BLISTER study website: **www.blistertrial.co.uk** or you can contact us for more information (see below).

You are very welcome to share the content of this newsletter with healthcare professionals as well as anyone else who you think may benefit from this information.

This study was only possible because so many people with bullous pemphigoid were willing to get involved. We'd therefore like to express our sincerest thanks to all the BLISTER study participants. By taking part in this research, you've helped give an extra treatment option to people who experience this disease in the future.

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