

STOP GAP

Patient Newsletter

The STOP GAP trial was a huge collaboration involving healthcare professionals, researchers and patients from across the UK, and is the largest pyoderma gangrenosum trial in the world.

We have now finished analysing the data, and are pleased to share the results with you. We'd like to thank you all for your help with the study.



Background information

Why was a trial needed?

Pyoderma gangrenosum is a relatively rare condition but it is still important that we understand which treatments work best, how quickly they have an effect, and what the side-effects are likely to be.

Ciclosporin (a drug that affects the immune system) and prednisolone (a steroid medication) are the two most commonly prescribed treatments for pyoderma gangrenosum, but no clinical trials had previously examined how safe and effective they are for treating this condition.

What did the trial involve?

Participants were randomly divided into two groups and treated with ciclosporin or prednisolone. Participants were monitored for up to 6 months whilst their ulcers healed.

Because we wanted to gain as much information as possible about pyoderma gangrenosum treatments, we also ran another study alongside the trial that collected information on the effectiveness of ointments and creams.

Patient involvement in trial design



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It is very difficult to recruit sufficient patients to studies of rare and serious diseases such as pyoderma gangrenosum. STOP GAP has achieved impressive recruitment [and the evidence it has produced] will guide clinicians in offering patients treatment that is as safe and as effective as possible.

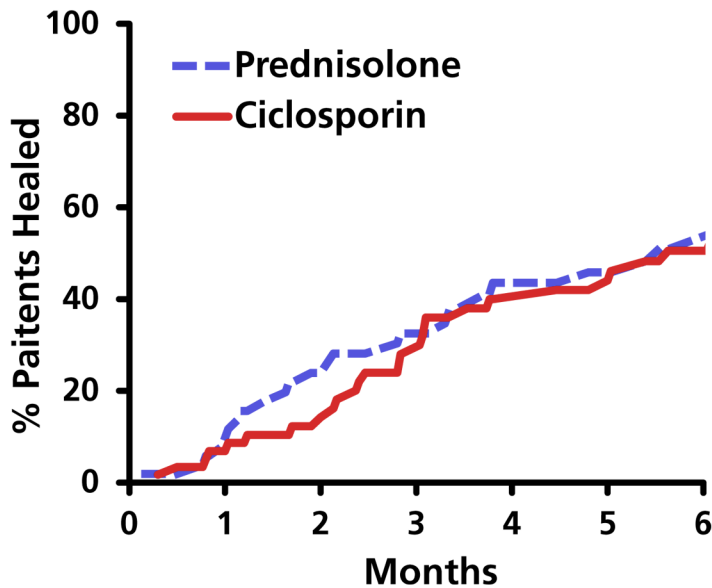
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Dr Nick Levell,
Doctor involved in the
STOP GAP Trial

Getting patient input during the early stages of designing a trial is a crucial step that can really help to improve the way a trial is designed and run. Before starting the STOP GAP trial we asked patients and doctors for their views on what we planned to do.

- We made sure that we were asking a question about pyoderma gangrenosum ulcer treatment that both patients and doctors thought was important.
- Discussed with patients how people might be encouraged to join the trial.
- Asked patients with pyoderma gangrenosum and the doctors who treat them which medications should be compared.
- Conducted a small study before starting the main trial to test whether participants could take photographs of their pyoderma gangrenosum ulcers for themselves, or whether it was better to ask participants to return to clinic for photographs to be taken.
- Made sure that we were measuring the right things; patients told us that 'pain' and 'discharge from the wounds' were particularly important for them, so these aspects were measured during the trial.

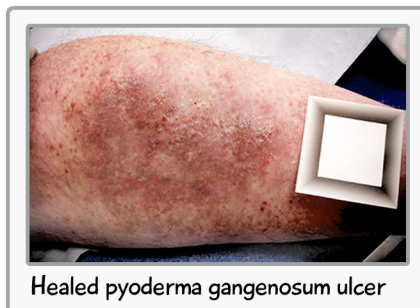
Results of the STOP GAP trial



The measurements taken during the trial (which included healing time, pain levels and treatment response) were compared for participants in the ciclosporin and prednisolone treatment groups.

We found no differences between the groups for any of the measurements collected. This means that **prednisolone and ciclosporin are equally effective** for the treatment of pyoderma gangrenosum ulcers, but the side effects of each medicine are slightly different. This is important as it means that patients and their doctors can choose which treatment is best for them based on their individual health needs.

It was a surprise to us that less than half of participants' ulcers healed despite 6 months of treatment. We also found that 1 in 3 participants had another ulcer during follow-up. These findings would suggest that better treatments need to be found and tested.



The separate study looking at creams and ointments found that medications, like strong steroid ointments, may be effective for treating smaller ulcers, but that these medications may work more slowly.

What will happen with these results now?

We are working hard to make sure these results are shared as widely as possible.

As patients with pyoderma gangrenosum often have other conditions (such as rheumatoid arthritis or inflammatory bowel disease) they may receive treatment from doctors who are not skin-specialists.

We are therefore making sure that the results are written and discussed in places where all doctors are likely to see people with pyoderma gangrenosum.

The results of the study have already been presented at international conferences and have been published in The British Medical Journal (BMJ):

<http://www.bmj.com/content/350/bmj.h2958.full>

You can help us spread the results of the STOP GAP trial by sharing this newsletter with your doctor.



Who conducted the STOP GAP trial?



Tony Ormerod
(Lead Clinician)



Hywel Williams
(Chief Investigator)



Eleanor Mitchell
(Trial Manager)

Treatments for pyoderma gangrenosum were identified as an important area for research by members of the **UK Dermatology Clinical Trials Network**. This network is an independent voluntary group of doctors, nurses, researchers and patients who are interested in developing high-quality evidence for the treatment

and prevention of skin disease. The trial was first suggested by Professor Anthony Ormerod from Aberdeen, who has a special interest in pyoderma gangrenosum. However, this work would not have been possible without the help of doctors and nurses from 39 different hospitals throughout the UK - most of whom contributed their time and support for the STOP GAP trial on a voluntary basis. The study was funded through a research grant from the **National Institute for Health Research (NIHR)**, which is the research arm of the **National Health Service (NHS)**.

We hope that you have found this summary informative. The results of this research will ensure that future patients with pyoderma gangrenosum are able to make more informed treatment choices based on this evidence provided by these two studies.

Thank you once again for your support and contribution to this work

If you would like more information about this research, please visit our website:

www.stopgaptrial.co.uk



National Institute for Health Research