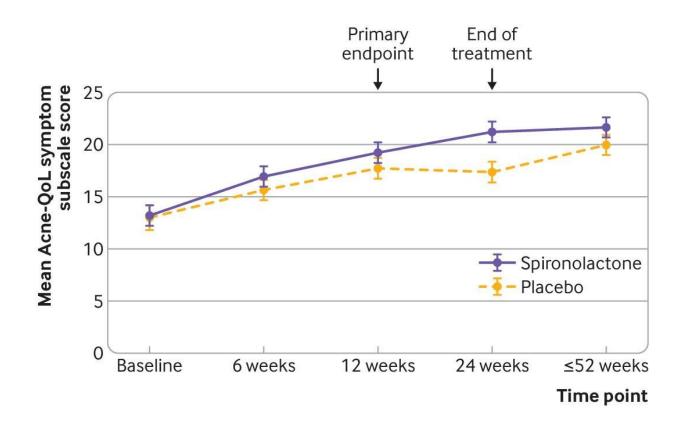


Non-antibiotic treatment for women with persistent acne shown to be effective

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Mean Acne-QoL symptom subscale score by time point for each treatment group. QoL=quality of life. Credit: *BMJ* (2023). DOI: 10.1136/bmj-2022-074349

A team of researchers led by the University of Southampton has shown that a cheap and readily available drug, used to treat high blood pressure, could help the thousands of women who suffer from persistent acne.



The SAFA study is the first large-scale clinical trial to provide evidence that spironolactone is an effective treatment for the skin condition.

The results of the trial have been published in *The British Medical Journal* today.

It's expected the results will change in the way <u>acne</u> in women is routinely treated—improving patient outcomes and reducing the large number of antibiotics currently prescribed for the condition.

"We hope the publication of these results will mean more GPs and dermatologists feel confident to prescribe spironolactone as a treatment for acne," says Professor Miriam Santer, GP and Professor of Primary Care Research at the University of Southampton and co-lead of the trial. "The drug is already included in treatment guidelines for persistent acne in the U.S. and Europe, and we hope this trial will lead to a change in the U.K. guidelines."

A need for new treatments

Almost a third of women who have acne in adolescence continue to be affected in adulthood. This can be a huge physical and psychological burden to those who suffer from persistent outbreaks.

Topical treatments (creams and gels), available from a pharmacy or on prescription, are the first-line treatment for acne. They are effective for many people, but if they don't work then GPs will often prescribe oral antibiotics to be used alongside the creams and gels. This can add to the growing burden of antibiotic resistance in the population.

"For several years, dermatologists have been prescribing a drug called spironolactone to treat severe acne," says Professor Alison Layton from Harrogate and District NHS Foundation Trust and the Skin Research



Center at the University of York, and co-lead of the SAFA trial. "This is a cheap medication which has been used for decades in the treatment of high-blood pressure. The drug also reduces the main hormone that leads to the development of acne."

"However, previous studies of spironolactone for acne have been very small and there was no definitive proof that it actually worked."

An effective treatment

The SAFA trial recruited over 400 women, aged over 18, with acne that had persisted for more than six months and where oral antibiotics would have normally been the next treatment. Half were randomly allocated to take spironolactone, while the other half were given a placebo.

The women were asked to complete questionnaires on their acne and quality of life relating to the condition at the start of the trial and then at 12 and 24 weeks into their treatment.

"The results showed that the women taking spironolactone saw a significant improvement in their acne after 12 and 24 weeks compared to those on the placebo," says Professor Santer.

"A significantly higher proportion of people also reported that they felt satisfied that their skin had been helped compared with those receiving placebo, and any side effects were uncommon and very minor. These results show that spironolactone could offer an alternative to antibiotics for many women with persistent acne to use alongside topical acne treatments."

Making a real difference

Kelly Cornick, 39, began suffering with severe acne in her teens and



since then has been prescribed various creams and antibiotics as well as the contraceptive pill to try and control her skin.

"Nothing seemed to work," says Kelly. "It might go away for a while, but then it would flare up again. It was sore, almost like blisters. I would get thick, red, lumps all along my jawline and at its worst it spread up onto the rest of my face. If I knocked a spot, it would really hurt and would bleed for ages. It was just horrible."

The mum of three from Dorset says it had a huge effect on her both physically but also psychologically.

"It was embarrassing. People would stare and you almost feel that they're looking at you like you're dirty and don't wash properly. I think the worst thing for me was when one of my nieces said, 'have you got chicken pox." She was only about two and kids are always quite honest, but that's how bad it looked. It used to get me down. I'm a confident person but my skin just took over how I felt a lot of the time."

Kelly was told about the SAFA trial by her dermatologist and contacted the trial team at Poole Hospital.

"Initially I started on the lower dose and there was an improvement. I then went onto the higher dose and within about three months everything was gone, all the spots had disappeared."

Since finishing the trial, Kelly has been able to stay on spironolactone and has now been acne-free for over two years.

"Knowing how much it's helped me, I hope that other people will now be given this treatment as an option instead of just trying the antibiotics. I want people to be able to experience it, because everyone should feel confident and happy, and not have spots."



Positive results

Zina Eminton, Senior Trial Manager at the Southampton Clinical Trials Unit said, "This was a challenging trial which began just as the COVID-19 pandemic hit the U.K. This meant we had to adapt to be flexible and agile in the way the trial was run, using social media to help recruit participants and conducting follow-up appointments virtually over video calls. Seeing these positive results published today is a fantastic achievement for everyone involved and we believe will benefit many more women in the future."

Professor Andrew Farmer, Director of NIHR's Health Technology Assessment Program, said, "The findings from this important trial provide compelling evidence which could help thousands of women affected by persistent acne. The treatment provides a valuable alternative to antibiotics and ensures clinicians can also better avoid the harms that can arise from antimicrobial resistance.

"High quality, independently funded research like this is crucial in providing evidence to improve health and social care practice and treatments."

More information: Miriam Santer et al, Effectiveness of spironolactone for women with acne vulgaris (SAFA) in England and Wales: pragmatic, multicentre, phase 3, double blind, randomised controlled trial, *The BMJ* (2023). DOI: 10.1136/bmj-2022-074349

Provided by University of Southampton

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