

AVURT: aspirin versus placebo for the treatment of venous leg ulcers – a Phase II pilot randomised controlled trial

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Plain English summary

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Plain English summary

We conducted a small randomised controlled trial to look at whether or not a daily dose of 300 mg of aspirin may help to heal venous leg ulcers. The aim of the trial was also to enable a decision to be made about whether or not a large trial should be undertaken to confirm our results. We also looked at whether or not aspirin is safe to use in people with leg ulcers. We aimed to recruit 100 patients from leg ulcer clinics. Half of the patients recruited received 300-mg capsules of aspirin and the other half received a dummy drug (placebo). Both groups also received the usual ulcer treatment of compression therapy and dressings. Participants and doctors were unaware whether an individual had received aspirin or the dummy drug.

We measured how long it took the largest ulcer to heal as the main measure of treatment success. We also measured changes in the size of participants' reference (largest eligible) ulcer over 6 months using photographs and tracings of the wound outline, and collected information about the amount of pain caused by the ulcer, how often participants took the study drug and the number of visits participants had to the hospital or their general practitioner.

We concluded that a larger trial recruiting the same type of patients would not be possible as we recruited only 27 participants instead of the 100 participants that we were aiming for. The main reasons that we could not recruit more patients in the time available were that many patients were already taking aspirin and/or their ulcer was smaller than the ulcer size we were investigating. Aspirin appears to be safe in this population; however, because we only recruited a small number of participants, we were unable to confirm if it might be effective for healing leg ulcers.

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