

Dear xxxxx

We are writing to update you with important information about the DiPALS study in which you are a participant.

At the last safety meeting the results indicated that pacing was of no benefit to patients with ALS and may in fact be causing harm. **The safety committee has therefore advised that all patients stop pacing.**

You were not receiving pacing and therefore this decision does not directly affect you. You should however continue to use Non Invasive Ventilation (NIV). This is a safe and effective treatment for breathing problems in ALS patients.

Although we have asked participants in the pacing arm to stop pacing it very important to continue to monitor all individuals for safety reasons and to gain as full a picture as possible regarding the effects of pacing in patients with ALS. We would therefore ask you to continue with your study visits until your 12 month visit or the planned end of the study.

The full study results are not yet available and will not be available until the end of the year or early next year. However, it is clear that pacing adds no benefit to the group of ALS patients included in the study. We will hopefully have more of an understanding when we have had the opportunity to analyse the full study results.

We understand that this may generate many questions. Your study team is available to answer your questions in detail.

We would like to take this opportunity to thank you for your contribution to DiPALS. We realize that taking part in clinical studies is itself a burden on individuals and those who support them. DiPALS is an important study and when the full results are available will help doctors and individuals with ALS to be able to make informed decisions about the best treatments for ALS.

Yours sincerely,
Local PI team