

DEVELOP-UK

A Study of Donor Ex-vivo Lung Perfusion
in United Kingdom Lung Transplantation
ISRCTN: 44922411

End of Study Information Sheet

This information is being provided to you because you took part in the DEVELOP-UK research study while waiting for lung transplant. The study compared a new technique called Ex-Vivo Lung Perfusion (EVLV) with standard lung transplant. We asked the research question: is EVLP an effective way to increase the number of donor lungs available for lung transplantation in the UK? The study follow-up period has now ended, and this Information Sheet is to inform you of what happens now, and to explain how to access the study results, if you wish to do so.

You were informed when you gave consent what would happen to you when the study ended, via the Participant Information Sheet (PIS).

DEVELOP-UK is an observational study that followed what happened to participants during their first year after transplant. Therefore you will continue to receive standard medical care now the study has ended, as you did throughout your participation during the first year.

No samples of tissue or blood were collected from you that were not part of your standard medical care after transplant. However, when applicable the research team took small samples of lung tissue from donor lungs at the start and end of the EVLP process. These samples are currently being studied by the research team to help understand how EVLP works. Some of this work might be done in partnership with other research organisations or companies both inside and outside the UK. No identifiable personal information (from either donor or recipient) accompanies these samples.

The results of this study are currently being evaluated and will be published in widely read medical journals that review the quality of the results, and will be presented to doctors and scientists at national and international medical meetings. The results will also be reported to the Sponsor (The Newcastle upon Tyne Hospitals NHS Foundation Trust) and Funders (National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme, and Cystic Fibrosis Trust). The results will also be available on the study website once evaluation is complete: www.develop-uk.net; you can access this, if you so wish. As a trial participant you will not be identified personally in any publication, study report or presentation.

If you have any further questions, or would like to continue your involvement in clinical research, please contact the study team at your participating hospital.

Many thanks for your interest and participation in the study; you have made a vital contribution to research and the improvement of healthcare for patients waiting for lung transplantation in the future.