General Data Protection Regulation (GDPR) Participant Information

Hemem arginate in transplantation study – a multi-centre blinded parallel-group randomised trial of heme arginate versus placebo to reduce delayed graft function in kidney transplant recipients. (HOT2 Trial)

The EU General Data Protection Regulation (GDPR), along with the new UK Data Protection Act, will govern the processing (holding or use) of personal data in the UK.

You are receiving this as you are currently a participant on this clinical research study. The information below details what data is held about you and who holds or stores this.

University of Edinburgh and NHS Lothian are the co-sponsors for this study based in the United Kingdom. We will use information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The co-sponsors will keep identifiable information about you for 15 years after the study has finished.

As a University/ NHS organisation we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Providing personal data directly e.g. verbally, in a questionnaire or from your care provider

The NHS Hospital Trust where you are taking part in the research will use your name, date of birth, NHS/ Community Health Index (CHI) number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Edinburgh/NHS Lothian and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The NHS Hospital Trust where you are taking part in the research will pass these details to the University of Edinburgh and NHS Lothian along with the information collected from you and your medical records. The only people in the University of Edinburgh and NHS Lothian who will have access to information that identifies you will be people who need to contact you to carry out follow up activities, as detailed in the participant information sheet, or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

The NHS Hospital Trust where you are taking part in the research and the University of Edinburgh/NHS Lothian will keep identifiable information about you from this study for 15 years after the study has finished.

Providing personal data indirectly e.g. from your medical records

The Co-sponsors (University of Edinburgh and NHS Lothian) will collect information about you for this research study from you directly and from your medical records. This information will include your name, NHS/ Community Health Index (CHI) number, contact details, your date of birth, gender, ethnicity and health information, which is regarded as a special category of information. We will use this information to meet the objectives of the HOT2 Trial and for audit of the data collection process. Your NHS/CHI Number will be used by the co-sponsors organisation to obtain long term (1 year) follow up information from the central Organ Donation and Transplantation (ODT) database. The information that will be obtained from ODT is routinely collected clinical information regarding your recovery post-transplant. We will also use your contact details to carry out the follow up visits at 1 and 3 months post-transplant, including sending the quality of life questionnaire to you for completion and return.

Use of data for future research

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Contact for further information

You can find out more about how we use your information and our legal basis for doing so in our Privacy Notice at www.accord.scot.

For further information on the use of personal data by NHS sites, please link to the Health Research Authority (HRA) website; https://www.hra.nhs.uk/information-about-patients/.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/.

Data Protection Officer contact information:

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh
EH8 9YL
Tel: 0131 651 4114
dpo@ed.ac.uk

NHS Lothian
Data Protection Officer
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5444
Lothian.DPO@nhs.net