GENERAL DATA PROTECTION LEGISLATION (GDPR) 2018
DATA PRIVACY STATEMENT
PARTICIPANT INFORMATION

ARTemis TRIAL

Dear Study Participant,

The ARTemis Trials Management Group would like to thank you for your participation in the ARTemis Trial. Participation in a clinical trial is an important step that benefits public health and promotes medical knowledge.

We are contacting you as new legislation in the European Union regarding personal data, the General Data Protection Regulation (GDPR), has been introduced. This new legislation came into effect on May 25, 2018 and includes additional rules on how companies, organizations and agencies may use your personal information. Part of the new legislation stipulates that we need to provide you with additional information. This information is being provided to you in addition to the information you already received with the patient information and informed consent at the beginning of the study. We are required to inform you of the procedures in place for processing and storing your personal data for research. This is considered to be a 'task in the public interest'.

Will my taking part in this trial be kept confidential?
Cambridge University Hospitals NHS Foundation Trust (CUH) and The University of Cambridge (UoC) are the Sponsors for this clinical trial based in the United Kingdom. They will be using information from you and your medical records in order to undertake this trial and are the 'data controllers' as defined in the GDPR. On behalf of the Sponsors this information is also transferred to University of Warwick, Clinical Trials Unit (UoWCTU) where the trial has been co-ordinated and the data collected, stored and analysed. The UoWCTU is the 'data processor' as defined in the GDPR. Both the data controller and the data processor are responsible for looking after your information and using it properly. The Sponsor organisations and data processors will keep identifiable information about you for a minimum of 5 years after the trial has finished.

Your rights to access, change or move your information are limited, as the Sponsor organisations need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how the Sponsors, data controller and data processor use your information using the information below:

- For Cambridge University Hospitals NHS Foundation Trust (Sponsor and Data Controller), please visit: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk

- For University of Cambridge (Sponsor and Data Controller) please visit: https://www.medschl.cam.ac.uk/research/information-governance/, or email the Information Governance team at: researchgovernance@medschl.cam.ac.uk

For University of Warwick, Clinical Trials Unit (Data Processor), please email - gdpr@warwick.ac.uk

PLEASE DELETE AS APPROPRIATE.

For participants recruited at CUH (where the Sponsor is also the site):
Cambridge University Hospitals will collect your name, date of birth, NHS number, hospital number and contact details, to be able to contact you about this trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this trial. Cambridge University Hospitals will pass these details to the Sponsors and the data processor (at UoWCTU) along with the information collected from you and your medical records. The only people in the Sponsor organisations and UoWCTU who will have access to information that identifies you will be people who need to contact you in relation to this trial, to send you follow up questionnaires and to audit the data collection process. Cambridge University Hospitals will keep identifiable information about you from this trial for a minimum of 5 years after the trial has finished.

For participants recruited at other participating sites:
(Add site name) will keep your name, date of birth, NHS number, hospital number and contact details to contact you about this trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Certain individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this trial.

(Add site name) will pass personal information about you (Initials, date of birth, NHS number, Hospital number) to the Sponsor organisations and the data processor (at UoWCTU) in order to send you follow up questionnaires, and to monitor your long-term health via the NHS national registries.

(Add site name) will keep identifiable information about you from this study for **(Insert number of years)** years after the study has finished.

All information collected about you as a result of your participation in the trial will be kept strictly confidential. Your personal and medical information will be kept in a secured file and be treated in the strictest confidence.

When you agreed to participate in this trial you were allocated a Trial ID Number. This is a unique trial number which will be used on all your trial documentation along with your initials, date of birth and hospital number. Your date of birth is considered to be personal information. We collect this personal information on trial documentation to help ensure that the data we receive as part of your trial participation is correctly allocated to you. By cross checking these unique references we can ensure the integrity of the data.

The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Only anonymous trial data, without any personal information will be published at the end of the trial.

When you agreed to take part in this trial, the information about your health and care may be provided to researchers running other research studies in this organisation and

in other organisations. 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. Once the ARTemis Trial results are published, conditions for data-access agreements will be developed and applications for data from the trial will be considered by the ARTemis Trial Management Group.

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.

For further information regarding the trial, the Sponsors and data processor, will work with your responsible consultant and the team at your hospital to contact you directly about the trial. If necessary, the Sponsors will collect information about your progress in this trial from your GP or through the Office for National Statistics. This information will include your name and NHS number and health information, which is regarded as a special category of information. We will use this information to complete your follow-up in the trial if this is not available via your responsible consultant. Consent for this was included on the ARTemis Patient Information Sheet and Informed Consent Form which you signed when you consented to take part in the study.