The University of Manchester

INSERT LOCAL HEADER / TRUST LOGO

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Phase II trial of Interleukin-1 receptor antagonist in intracerebral haemorrhage: BLOcking the Cytokine IL-1 in ICH Short title: **BLOC-ICH**
IRAS Ref: 252065 EudraCT: 2018-000249-38

Participant Information Sheet

This Information Sheet should be read in conjunction with the University of Manchester privacy notice found at the following link: http://documents.manchester.ac.uk/display.aspx?DocID=37095, via the BLOC-ICH trial website, and by contacting the trial team (0161 206 5755). A paper copy is also available on request.

You are invited to take part in a clinical trial of a drug which may reduce inflammation after haemorrhagic stroke. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

Who will conduct the research?

The trial is led by the Chief Investigator, Dr Adrian Parry-Jones at The University of Manchester, together with Manchester Clinical Trials Unit (Manchester CTU), who will oversee the running of the trial at all trial centres. This trial will recruit participants from a number of hospitals in England and Scotland. The trial is sponsored by the University of Manchester.

What is the purpose of the project?

We are interested in developing a new treatment for intracerebral haemorrhage (ICH). This is a type of stroke caused by spontaneous bleeding in to the brain. In the hours to days after bleeding occurs, we know that inflammation develops in the brain around the haematoma (collection of blood in the brain).

Although inflammation is the body's natural response to injury, when it continues unchecked it can worsen any damage. There is a risk that the brain tissue around the clot will become

swollen. This can worsen some stroke symptoms such as speech disturbance and limb weakness. These symptoms may be temporary, but can in some cases be permanent and lead to long term disability.

We know from previous studies that the level of inflammation in the blood is high after ICH and we want to investigate whether blocking this inflammation can improve outcomes. The only current treatments for ICH are aimed at significantly reducing the blood pressure and reversing of the action of any anticoagulants (e.g. warfarin) where necessary. Surgery to remove the blood clot is not an option for all patients and the benefits of surgery are not clear.

Our research group has extensively investigated the use of a well-established anti-inflammatory drug, Kineret® in trials with patients who have suffered a stroke or brain haemorrhage. Kineret® is similar to a naturally-produced protein called interleukin-1 receptor antagonist (IL-1Ra) and is already licensed to treat patients with rheumatoid arthritis. We have evidence from these previous studies that Kineret® reduced levels of inflammation in the blood after ischaemic stroke (caused by a blockage in an artery). In another trial, we have collected samples of the haematoma removed during surgery in 47 patients who had suffered an ICH. These patients were taking part in a trial of 'keyhole' surgery as a treatment for ICH. We found that higher levels of naturally-occurring IL-1Ra in and around the haematoma is linked to less brain swelling a few days later. This suggests that Kineret® may reduce swelling in the brain after ICH. However, in order to develop Kineret® as a treatment for ICH, we need to know if it reduces levels of inflammation present in the blood and if it reduces swelling in the brain.

In order to do this we plan to recruit patients who have suffered an ICH to this trial. Participants will receive 6 injections of identical doses of Trial Drug (Kineret® or placebo) over 3 days after ICH.

However, only half the patients will receive Kineret® and the other half will receive placebo (dummy drug). We will measure and compare levels of inflammation in the blood of both groups of patients before and after treatment with Trial Drug to assess if inflammation is lower in those who receive Kineret® compared to those given placebo.

We will also assess all brain imaging performed on trial participants in both treatment groups during their in-patient stay to see if there are differences in the number showing signs of further bleeding and brain swelling.

If the results of this trial show promise, it could support the decision to run a much larger trial to establish whether lowering inflammation improves recovery after ICH.

What is Kineret® and how does it work?

Kineret® (generic name anakinra) is the man-made form of IL-1Ra (interleukin-1 receptor antagonist). It prevents the protein IL-1 from attaching itself on to cells, and so prevents it from worsening inflammation. Kineret® has been used clinically in many patients with rheumatoid arthritis and other inflammatory diseases and by NHS researchers in stroke and brain injury.

Why have I been chosen?

You have been identified as having had ICH within the last few hours and may be eligible to participate in this trial (see below Confirming Eligibility).

What will happen to me if I take part?

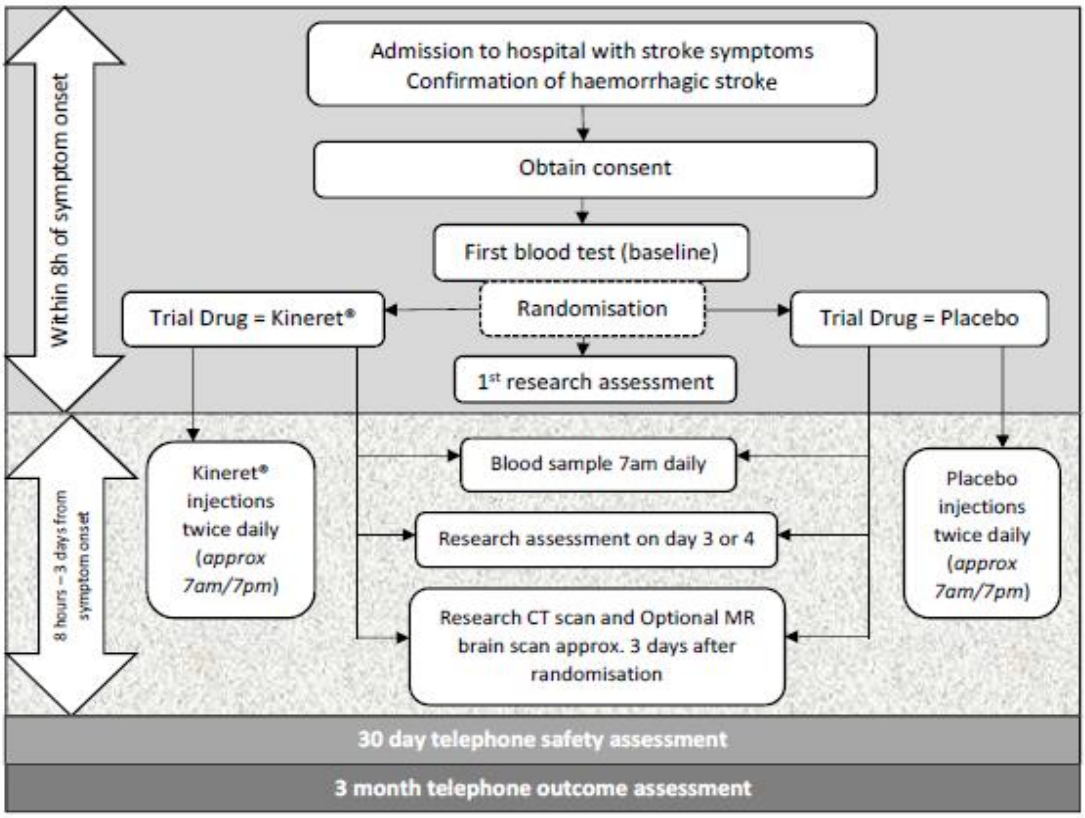
If you decide that you would like to take part, the treatment you receive will be identical to that received by anyone not taking part in the trial, with the addition of the Trial Drug (Kineret® or placebo) and the procedures described in the table below.

Members of the research team will start to check if you are eligible to participate in the trial immediately following your admission to hospital after stroke. If you are considered to be eligible you will be asked to read this information sheet. If you wish to participate you will be asked to confirm your consent by signing a consent form. If you are unable to sign the form yourself, a member of your family or your personal legal representative may sign this on your behalf to confirm that they have witnessed your verbal consent.

The first dose of Trial Drug (Kineret® or placebo) must be given within 8 hours of symptom-onset. If you are unable to decide whether to participate in the trial within this time-frame, you will no longer be considered for trial participation. If for any reason you are not included in the trial, this will not affect your clinical care.

More details of trial procedures are given below:

Trial Procedures Flow Chart:



<u>Confirming eligibility to take part</u>:

Before we seek your consent to participate in the trial, we must ensure you are eligible and the research team will ask for your verbal consent to conduct this check.

The research team may ask you questions regarding your health but they may also need to check your medical records, including the results of any brain imaging and blood tests performed at admission or they may speak to your relative or general practitioner (GP).

Common reasons why you may not be eligible to participate would include;

- If you were undergoing cancer treatment
- If you have had certain vaccinations in the last month
- If you were taking certain treatments for inflammatory conditions such as rheumatoid arthritis, ulcerative colitis or Crohn's disease.
- If you are female and of child-bearing age, it will also be necessary to confirm you are not pregnant (see below).

Please tell the researcher if you think any of these may be applicable or if you wish to discuss these in more details. If you are eligible and you wish to participate, you will be asked to confirm this by signing a consent form.

What is randomisation?

In order to find out whether a possible new treatment really works, we need to know whether people who receive that treatment are better than they would have been without it. This is achieved by conducting a randomised controlled trial, in which patients are allocated randomly to receive the treatment being tested or a dummy drug (placebo) treatment. Randomisation is organised by people independent of the research team. In this trial half the participants will receive Kineret® and the others will receive placebo which will be identical in appearance to the Kineret®, so the trial is designed in a way that no-one directly involved in the trial should know which treatment has been received until the trial has completely finished.

Administration of Trial Drug (Kineret® or placebo): The first dose of trial drug will be given as injection within the first 8 hours after onset of stroke symptoms. A further 5 doses of trial drug will be administered, at approximately 12 hourly intervals (morning and night) with the last dose given within 74 hours of symptom onset.

Blood sampling: Following your consent and before you are randomised to either Kineret or placebo, a small sample of blood (up to 2 teaspoons, 10ml) will be obtained for research purposes.

Up to 5 further research blood samples will be collected on each of the three days after your stroke. The final blood sample will be taken in the morning after the last dose of Trial Drug has been administered.

All blood samples will be no more than 2 teaspoons (10 ml) and will be collected at approximately 09:00am by a research nurse from a vein in your arm. The blood samples will be used to measure levels of inflammation and are in addition to your clinical care.

Research Assessments: Following your consent and allocation of treatment group (Kineret or placebo), the research nurse will conduct a number of research assessments, details of which will be written in your medical notes and also in an individual research file (Case Report Form). See the flowchart and below for more information.

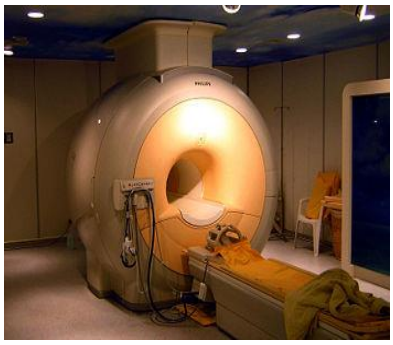
This first assessment will be used as a 'baseline' and will record details of how well you were at the time of inclusion in the trial as well as how well you were in the 3 months before your stroke. Information such as your age, sex, ethnicity and past medical history (including recent infections, previous stroke, risk factors, medications and vaccinations) will also be recorded. The results of the physical assessments used to measure your conscious level and physical ability after stroke will be recorded by the research team. These assessments are usually performed routinely by the clinical doctors after a stroke, but not, if they will be performed by the research team as part of the research assessments at baseline and again on day 3 after your stroke. On the morning after the final injection has been given the research team will ask you to verbally reconfirm your consent for your contact details to be passed to the coordinating centre (Chief Investigator's Team at University of Manchester).

Brain Imaging: At approximately 3 days after randomisation, you will undergo a repeat CT brain scan as part of the research trial. This scan is the same type as the one performed at admission. Although this scan is being performed as part of the research trial, the results will also be available to the doctors looking after you and may assist them in deciding on specific treatments. This scan will take approximately 10 minutes to perform but you may be away from the ward or department for up to 45 minutes. The scan will be used by the researchers who will compare it to brain imaging performed on admission to hospital.

In addition to the CT scan above, you may also be asked to undergo a Magnetic Resonance (MR) brain scan between 2-4 days from the onset of your stroke. This is optional and is dependent on availability of scan appointments at your hospital.

The MR scan produces detailed pictures of your brain and allow us to see any blood within the brain. This type of scan also allows us to see clearly any swelling that may be there as a result of the haemorrhage and whether the blood vessels around the blood clot, or elsewhere in the brain have become 'leaky'.

MR SCANNER:



MR scans are routinely performed after strokes and do not involve exposure to any X-rays or radioactivity. We will have completed a questionnaire with you to ensure you are able to undergo MR scanning. We expect the MR scan to last no more than 45 minutes. During the scan you will be injected with a special dye via the cannula already in your arm. This is used to see specific areas of your brain in more detail.

Safety: As with all clinical drug trials, it is necessary to confirm the safety of the Trial Drug being investigated. Members of the research team at the recruiting hospital will record everything that happens to you during your in-patient stay. This safety check will be performed before the second injection and after the final injection and will be checked again at 30 days after randomisation. If you are still in hospital on this date, this assessment may be performed face-to-face by a member of the research team. However, if you have been discharged home or returned to your local hospital, the researcher will perform this assessment by telephone with you, or your relative/friend if you are not able or your local healthcare provider. It is expected that this assessment will take around 45 minutes.

Follow up: You will be contacted by telephone at approximately 90 days (3 months) by a member of the research team at the trial coordinating centre in Manchester. This assessment will assess your recovery after ICH and will include questions about your mood, level of fatigue and quality of life. It is expected that this assessment will take around 45 minutes. If for any reason, you are unable to complete this assessment yourself, a member of your family may answer the questions on your behalf. This will complete your participation in the trial.

With your permission, the researchers at the recruiting hospital would like to contact your family doctor (GP), Consultant and any other Health Care Professional involved in your care to let them know that you have been a participant in the trial.

If necessary, the research team may contact your GP to ask them to provide information about you during trial participation and in particular, at three months after ICH if it is not possible to obtain this information from you or your relative.

Are there any alternative treatments?

No, there are no current alternative treatments to reduce inflammation following ICH.

What will happen to my personal information?

In order to undertake the research project we will need to collect some personal information/data about you which will include your name, telephone number, address and contact details for your GP. This information will be retained by the coordinating centre in Manchester until after completion of the final telephone assessment, after which time it will be destroyed. Only the clinical team at your recruiting hospital and the coordinating centre in Manchester will have access to this information.

Your medical notes and research record may also be seen by authorised people who are not directly involved in your care in order to check the conduct of the trial. Details are included in the complaint section of this sheet.

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect personal information. The legal basis upon which we are using your personal information is "public interest task" and "for research purposes" if sensitive information is collected. For more information about the way we process personal information and comply with data protection law, please see our Privacy Notice for Research Participants (details on how to access Privacy Notice can be found at the top of page 1 of this information sheet).

The University of Manchester, as Data Controller and Data Processor for this trial, takes responsibility for the protection of the personal information that this study is collecting about you. In order to comply with the legal obligations to protect your personal data the University has safeguards in place such as policies and procedures. All researchers are appropriately trained and your data will be looked after in the following way:

- The study team at the University of Manchester will have access to your personal identifiable information, that is data which could identify you, but they will anonymise it as soon as the three month telephone follow-up is completed.
- Your anonymised data will be kept on the electronic data capture system provided by Manchester Clinical Trials Unit.
- The University of Glasgow, Clinical Trials Unit (Robertson Centre) will manage the randomisation system and hence, will have access to participant identifiable data.

- The consent form signed by you, the research record and other study data held by the recruiting hospitals, University of Manchester and University of Glasgow will be archived and kept for up to 25 years.

In order to ensure we have an accurate record of your history and clinical presentation, research staff at the recruiting hospital will also need to access your clinical records. Personal contact information will also be shared with the Chief Investigator's team to allow them to conduct the final outcome assessment by telephone.

The trial is funded by the National Institute for Health Research (NIHR) and the Chief Investigator's team will follow the recognised guidelines regarding the sharing of trial data. This means that with your permission the anonymised data from the trial will be available to others.

Trial Drug has been provided free of charge by our collaborating drug company, Swedish Orphan Biovitrum (Sobi) – (see section below on publishing of study results).

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you. This is known as a Subject Access Request.

If you would like to know more about your different rights, please consult our privacy notice for research and if you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights. You also have a right to complain to the Information Commissioner's Office, Tel 0303 123 1113

Will my participation in the study be confidential?

Your participation in the study will be kept confidential to the study team and those with access to your personal information as listed above. All data will be anonymised once the three month follow up assessment is completed.

What happens if I do not want to take part or if I change my mind about participation?

If you do decide that you wish to take part you will be given this information sheet to keep and be asked to sign a consent form. However, you are still free to withdraw at any time without giving a reason and without detriment to your care. If you decide to withdraw from the trial, the

Chief Investigator's team seek your permission to retain the information that has been collected about you to the point of withdrawal. However, it will not be possible to remove your data from the project once it has been anonymised and forms part of the final dataset as we will not be able to identify your specific data.
This does not affect your data protection rights. You do not have to give a reason for withdrawing from the research and this will not affect the care you receive.

Anyone who takes part in the trial and has received at least one dose of Trial Drug who is then withdrawn from the trial (for example those who are discharged from hospital quickly) will be followed up for at least 30 days. As this is a clinical trial of a drug, we will need to continue to monitor your progress to confirm the safety of the drug. Where possible, the research team at the recruiting hospital will access information recorded in your medical records, rather than approach you in person.

As stated above, it is also your right to from the trial at any point without giving a reason. In this case the research team will continue to access your medical records for 30 days from the day you entered the study to monitor your progress and confirm safety of the drug. The clinical or research team at the recruiting centre may also withdraw participants if they consider it to be in their best interests.

If, for any reason your condition should change and you are no longer able to make decisions about trial participation, your original consent will remain valid. You will continue to participate unless your relative/friend requests that you be withdrawn or the medical team who are caring for you or the research team decide to withdraw you from the trial because they feel this is in your best interests.

Will my data and samples be used 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 (University of Manchester).

The future research should not be incompatible with this research project and will concern ICH. 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 regarding any other matter or to affect your care. It will not be used to make decisions about future services available to you.

The blood samples given by you will be prepared for analysis and temporarily stored by research staff at the recruiting hospital before they are transferred to the Chief Investigator's laboratories at the University of Manchester (Salford Biomedical Research Centre) for analysis. With your permission we would like to treat these blood samples as a gift. After the trial has finished, the Chief Investigator's team would like to keep components of your blood samples indefinitely. These blood samples will be transferred to a Research Biobank at the Chief Investigator's institution.

Blood samples will not be identified using names (see section on Confidentiality) and once the trial has completed, the link between your name and the ID code will be broken. If new knowledge about inflammation becomes available in the future, such as the discovery of a new measure of inflammation this will allow the samples to be used and avoids repeating studies where there are existing samples that can be used to investigate new research questions.

The Chief Investigator's team would also like to be able to use remaining components of the sample given by you to check the quality and consistency of the tests they carry out, and to develop new tests.

You are under no obligation for your samples to be used in this way and you will be asked to sign a consent form to allow your samples to be used for these purposes. These samples would only be used for research relating to inflammation, stroke and brain injury and would not be used to investigate other disorders.

Will I be paid for participating in the research?

You will not receive payment for taking part in the trial. The research staff will not receive any payment for your involvement in this trial.

What is the duration of the research?

If you decide to participate in this research, your participation will be for three months from the date of consent.

This will involve collection of all in-patient blood samples, recording of trial assessment data, performing the MR scan and CT scan, as well as the 30 day telephone assessment and three-month telephone follow-up assessments. For a full list of samples, scans and assessments involved in the participation of this trial, please see above section 'what will happen if I decide to take part?'

Will outcomes of the research be published?

The results of the trial will be submitted for publication to medical journals and at conferences. The results will also be submitted to authorities who are responsible for the development of new drugs to ensure they have all relevant information about the trial drug and the conduct of the trial. The results will also be sent to Swedish Orphan Biovitrum AB, who is also supporting this trial, as this information may be used to inform future trials of this drug. The results will be completely anonymised and your name or personal details will not be included.

If you wish to receive information about the results of this trial, these will be available on the University of Manchester website once the trial is complete in approximately 2020.

Confidentiality

If you decide to take part your hospital notes and other health records may be seen by authorised people (other researchers and people checking the study conduct). Anonymised copies (all personal details removed) of all brain CT and MR scans will be sent to the Trial Coordinating Centre (University of Manchester) and Johns Hopkins University, Baltimore, USA for additional analysis via a secure electronic data transfer platform. Your name will not appear in any publications arising from the study. All study documentation taken as part of the assessments and examinations will be identified using a unique code assigned to you after consent

Who has reviewed the research project?

Independent researchers in the field of stroke have reviewed the trial positively. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This trial has been approved by the Health Research Authority (HRA). This includes being given a favourable opinion by *to be inserted* Research Ethics Committee and has received approval from the Medicines and Healthcare products Regulatory Agency (MHRA).

What if I want to make a complaint?

Complaints: If you have a minor complaint then you need to contact the research team at your recruiting hospital in the first instance. If you have a concern about any other aspect of this trial, you should ask to speak to the local researchers who will do their best to answer any questions. If they are unable to resolve your concerns or you wish to make a formal complaint regarding the trial, please contact a University Research Practice and Governance Coordinator on 0161 276 7583 or 0161 275 8093 or by email to research.complaints@manchester.ac.uk.

Harm: In the event that something does go wrong and you are harmed as a result of participation in this trial, you may have grounds for a legal action for compensation against The University of Manchester or NHS Trust but you may have to pay your own legal costs. The normal National Health Service complaints mechanisms will still be available to you. Please ask a member of medical or research staff at your recruiting hospital for details of these.

Confidentiality: If you consent to take part in this trial, all information which is collected about you during the trial will be kept strictly confidential as required by Data Protection laws.

Once you are recruited into the trial, you will be allocated a unique trial identification number and all research records relating to your participation will use this number to ensure the record is anonymised.

What are the possible benefits of taking part?

IL-1Ra is the naturally occurring version of Kineret®. We have studied levels of IL-1Ra in the brain of 47 patients having ‘keyhole’ surgery for their ICH. We found that patients with more naturally-occurring IL-1Ra had less brain swelling a few days later. We believe that giving more IL-1Ra as Kineret® may help reduce swelling further and BLOC-ICH is designed to tell us if this is correct.

It is also possible that the trial will not have any direct benefits to your relative/friend, but they will be helping to increase what is known about recovery from ICH, inflammation and new treatments which could improve patient care in the future.

What are the possible risks of taking part?

Your well-being and safety is our primary concern. Most of the information about the side effects of Kineret® has been discovered from the treatment of patients with rheumatoid arthritis; many of whom have taken Kineret® for a long time (months or years). In this trial, treatment is very short (maximum of 3 days).

Common issues seen in previous trials of Kineret® in stroke and brain injury:

1. Injection site reaction: A known side-effect of Kineret® is the appearance of small, red and occasionally itchy patches on the skin where injections have been given. This is more common in people given injections for long periods (more than 10 days).

The injection site reaction disappeared when the treatment was discontinued and participants in previous trials did not request withdrawal because of this.

2. Blood Sampling: You may experience some discomfort and bruising caused by blood sampling. Researchers at the recruiting hospital will try to combine clinical and research blood sampling to minimise any discomfort.

3. Final Assessment: While not a side effect of the Trial Drug itself, some people may find the questions and assessments at the 3 month assessment distressing. The researcher performing the assessment is very experienced in completing the assessments and is mindful of the distress this may cause. You can refuse to answer any questions which you find upsetting and you can stop the assessment at any time.

4. Brain imaging: There are no expected risks or side-effects associated with additional CT brain imaging. A doctor or nurse from the research team will remain with you throughout the CT scan until you are returned to the ward or department. CT scanning involves a small dose of x-ray radiation equivalent to half of the yearly background radiation exposure.

MR scanning can be noisy in spite of the ear protection you will have to wear. Being inside the scanner can be claustrophobic and you may also have to keep still for long periods of time and have limited opportunity to adjust your position which can be uncomfortable.

You may have your head placed in a soft brace to ensure that you are correctly positioned. You will be closely monitored and a doctor will be in attendance at all times.

The dye that is injected during the MR scan may cause side effects in some people but these are usually mild and short lasting. Some of the more common side effects include injection site pain, nausea, vomiting, itching, rash and headache. Occasionally the injection may leak out from the vein to the tissues under the skin – this is known as extravasation. If this has happened, you will experience a stinging sensation where the contrast has gone into the tissue and it can be painful. Serious allergic reactions are very rare but can include swelling of face, mouth, hands, feet or throat, coughing and difficulty in breathing or swallowing. Most occur during the injection or within the first hour following administration. If you have any concerns about side effects, please speak to the staff caring for you.

The doctors who are looking after you and the researchers at the recruiting hospital will assess your fitness to undergo brain imaging on the day of scan. If you decide you do not wish to undergo brain imaging, you can decline at any time without affecting your participation in the trial.

Known risks/side-effects of Kineret® <u>not</u> seen in previous stroke trials:

Infections: Studies that have given Kineret® over short periods ranging from 1 day to 3 weeks (for severe infections; subarachnoid haemorrhage or stroke) and have shown no evidence of increased infections. However, studies in patients with rheumatoid arthritis who have been receiving Kineret® for a long time (months or years) have shown a slight increased risk of infections; some of which are classed as serious. People with stroke are often at increased risk of infections and so are monitored extremely closely by their clinical team so that these can be treated rapidly if they occur. Previous studies of Kineret® in stroke and subarachnoid haemorrhage have **not shown** an increase in infections.

Antibodies to Kineret®: Previous studies also showed that after long-term use of Kineret®, the body may make antibodies to IL-1Ra (found in Kineret®) with a possible risk of allergy. This is a rare but a potentially serious side effect.

If you think you may have received Kineret® (sometimes called anakinra®) before or a similar drug, either as part of your medical care or as part of another research trial, you may be excluded from taking part in this trial. The researcher at the recruiting hospital will be happy to discuss this issue.

Pregnancy

The effects of Kineret® on the foetus and nursing child are not known. If you suspect or know you are pregnant or are breast-feeding you cannot take part in the trial so you must inform the trial team. Prior to inclusion in the trial, if you are not able to reliably confirm you are not pregnant, it will be necessary to perform a pregnancy test.

Your verbal consent will be obtained beforehand. If you decline, you will no longer be considered for trial participation. **It is important that you (or if you are male, your partner) avoid becoming pregnant whilst receiving Trial Drug.**

What if new information becomes available?

Sometimes during the course of a project, new information becomes available relating to what is being studied. If this happens, a researcher will tell you about it and discuss if you want to continue in the trial. You may be asked to confirm your willingness to continue by signing a new consent form.

Contacting your GP

Your GP will be informed that you are taking part in this trial. This is standard practice and will ensure that your GP continues to be involved in their care.

What do I do now?

If you have any queries about the study or if you think you would wish to take part then please contact the research team at the recruiting hospital: ***<<to be inserted by local team>>***

THANK YOU FOR READING THIS INFORMATION