The ROAM Trial
Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial

<Trust/Site address 1>
<Trust/Site address 2>
<Trust/Site address 3>
<postcode>
Tel: <telephone number>

Adult Patient Information and Consent Form

www.roam-trial.org.uk/new/index_new.html

We want to invite you to take part in our research study. To help you decide, this leaflet will explain what the research is for and what it would mean for you. A member of our research team will go through this information sheet with you and answer any questions you may have.

Why is this study needed?

Meningiomas are brain tumours arising from the linings of the brain. Most of these tumours are benign (meaning non-cancerous, grade I) and can be treated with surgery alone. Very rarely these tumours are malignant (cancerous, grade III) and need treatment with both surgery and radiotherapy. There is another type of tumour, called atypical meningioma that falls between the benign and malignant group (these are grade II). Every year in the UK, about 150 patients with atypical meningiomas like yourself have surgery. After surgery, there is a chance that atypical meningiomas can grow again and we want to find out what is the most effective treatment for these tumours following surgery, to reduce the chance of the tumour growing back. So, we are doing a study to find out whether it is more effective to have further treatment after surgery (radiotherapy) or whether we should monitor patients with regular MRI scans (active monitoring).

So the study is comparing two treatments:

Surgery, Radiotherapy and active monitoring
or
Surgery and Active monitoring

The only way to find out which is the most effective is to do a study to compare these treatment groups. This type of study is called a Randomised Controlled Trial and will help doctors to advise patients about which is the most effective treatment in the future.

Why have I been chosen?

You have been asked to take part because you have recently had surgery to remove an atypical meningioma. We would like 172 patients from a number of hospitals across the UK, mainland Europe, Australia and New Zealand to take part in this study over a period of approximately 4 years.

Do I have to take part?

No, taking part is voluntary. If you do not want to take part in the study, you will be followed up after your surgery according to the standard policy for your hospital – this will usually be active monitoring but you can check this with your clinical team. Saying "no" will not affect the quality of care and treatment you would normally receive, and you do not have to give a reason.

If you join the study but later change your mind about taking part, that's okay too. No more information will be collected about you. All information collected up until this time will be included in the study analysis, unless you request that it is removed.

What are the alternatives for treatment?

If you have been approached for this study, the options for treatment for you are radiotherapy or active monitoring. Active monitoring means regular scanning. There are no other treatment options.

What will happen to me if I join the study?

If you decide to take part, you will be allocated to one of the two treatment groups, with equal chances of being in either the surgery, radiotherapy and active monitoring group or the surgery and active monitoring.

We will follow your progress, collecting information at 6 months, 12 months, and then annually until 5 years after your surgery. This would be part of your normal hospital follow-up. We will also ask your permission to contact you after the study has finished for future research projects.

Study design:

In this study we are comparing radiotherapy and active monitoring with active monitoring:

Surgery, Radiotherapy and active monitoring	**OR**	**Surgery and Active monitoring**
Radiotherapy involves giving patients small, carefully measured doses of radiation. Radiotherapy is painless and each session lasts a few minutes. Treatment will usually be given daily (Monday to Friday) for 6 weeks. Your treatment will start approximately 8-12 weeks after your surgery. After the radiotherapy treatment is completed, you will have follow up appointments at 6 months and 12 months, then every year until 5 years after your surgery. These appointments will involve having MRI scans, and doing questionnaires to assess your quality of life, memory, language, mood and related outcomes. We will also collect information about any adverse events, should you have one. An adverse event is something that happens that wasn't planned and is unfavourable. Follow up will be done by your treating neurosurgeon or oncologist.		Active monitoring involves close monitoring at 6 months, 12 months, and then every year until 5 years after your surgery. This will involve having MRI scans, and doing questionnaires to assess your quality of life, memory, language, mood and related outcomes. We will also collect information about any adverse events, should you have one. An adverse event is something that happens that wasn't planned and is unfavourable. The monitoring will be done by your treating neurosurgeon or oncologist.

It is important that doctors do the study like this as it is the only way to find out which treatment is most effective for patients with atypical meningioma. Neither you nor your doctor will choose which treatment group you will be in, as this is done by a computer programme that randomly assigns you to radiotherapy and active monitoring or active monitoring only.

We will also look at which approach to treatment is the most cost-effective – this is called a health economic analysis. To be able to do this, we need your NHS number, postcode and date of birth to collect information about your hospital admissions during the study (see *additional information below).

Are there any risks or benefits to me if I join the study?

There are no direct benefits for you being part of the study compared to people who do not participate. We hope that the information we get from the study will improve the treatment of other people with atypical meningioma in the future.

We want to find out whether active monitoring is sufficient to treat your tumour, or whether radiotherapy is needed. There are potential risks and benefits to both radiotherapy and active monitoring. We are doing this study to find out which is most effective.

Radiotherapy and active monitoring

Potential benefits:
Radiotherapy may control the meningioma meaning that no further treatment is needed in the future. We would still monitor you with MRI scans which are safe and painless. Data from a small previous study of radiotherapy showed excellent tumour control rates at 5 years, but there was no comparison with active monitoring.

Potential risks:
The majority of patients who have radiotherapy do not experience any lasting side effects. Side effects around the time of treatment are usually temporary and tiredness is the most common. Other side effects can include patches of hair loss (which usually regrows), scalp irritation and wound problems at the site where the radiotherapy is given, and headaches. Late side effects (years after treatment) may include some short term memory loss and hormone imbalance. There is a very low risk of developing other brain tumours. Modern radiotherapy planning means that the risks of late side effects are low and variable but most patients return to their usual activities within three to six months.

Active monitoring

Potential benefits:
The potential benefit of active monitoring is that after surgery you don't need any more treatment at this stage. Active monitoring involves MRI scans which are safe and painless.

Potential risks:
Some patients can feel anxious or worried about the results of each upcoming scan. If the tumour was to regrow, further surgery, radiotherapy or radiosurgery (focused radiotherapy) may be needed in the future. You may want to discuss this further with your clinical team.

What if there is a problem?

If you are worried about any aspect of this study, speak to the ROAM study team who will do its best to answer your concerns. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure which may be your local NHS Patient Advice and Liaison Service (PALS). Details can be obtained from the hospital that you are being treated in.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, you may have grounds for legal action for compensation against the NHS Trust where you are being treated. In this instance you may have to pay your own legal costs. The normal National Health Service complaints mechanisms should be available to you.

Will my taking part in this study be kept confidential?

Yes. Only people working on the study or working to ensure the study is run correctly will have access to the data (please see *additional information below). All information collected about you during this study will be confidential, with the exception of patient identifiers that will be shared with NHS Digital, and will be handled, stored and destroyed in accordance with the Data Protection Act 1998. You will be provided with a letter that will also be sent to your GP.

With your consent, we will use your NHS number and postcode to access data about your hospital admissions. This will, for example, involve sharing your personal details with NHS Digital in order for them to provide information already in their possession on your hospital attendances (including inpatient, outpatient and A&E attendances) and share it with members of the ROAM research team. The data NHS Digital provides to the ROAM research team will have your name, date of birth and other identifiers removed.

Will there be any additional samples taken?

Collecting blood and tissue samples during a study provides researchers with key information. The use of human samples is an essential part of this research and it will help to expand knowledge in the areas of how disease works, how disease can be prevented, diagnosed and treated.

During this study a dedicated facility (The Walton Research Tissue Biobank) will be used to store tumour and blood samples taken from patients taking part in the ROAM study. Ethical approval has been obtained to collect and store these tumour tissue and blood samples from patients in participating sites. A small amount of tumour tissue taken from your recent surgery will be sent to the biobank. Approximately 10 mls of blood (2 teaspoons) will be taken at each study visit and sent to the biobank.

We will apply for separate funding to carry out some additional research on the following:

1. The effects of radiotherapy on normal brain tissue situated next to the site where the tumour was removed
2. To look at whether inherited or other biological factors can be used to predict tumour recurrence and individual response to radiotherapy
3. To look at chemicals in your blood which may be used to predict tumour recurrence.

Consent:

If you would like to take part, and are happy with the research team's explanations, you will be asked to sign a consent form. *You will be given a copy of the signed consent form and information sheet to keep.*

What if new information becomes available?

The results of the study will be looked at from time to time by the study organisers. If any new information becomes available, the ROAM study team will discuss this with you

What will happen to the results of the study?

We aim to publish the results of this study in medical literature. Your confidentiality will be maintained at all times and you will not be identified in any publication. A short summary of the study will be provided on our website (www.roam-trial.org.uk/new/index_new.html).

*Additional information

ROAM is being run in the hospital where you are being treated, as well as other hospitals across the UK, Europe and Australia. The study is funded by the National Institute for Health Research's HTA Programme (Ref: 12/173/14) who have assessed the scientific merits of the study.

NHS
National Institute for Health Research

The Walton Centre NHS Foundation Trust are responsible for managing this study – they are the study Sponsor for the UK. The European Organisation for Research and Treatment of Cancer (EORTC) are the study Sponsor for Europe, and the Trans-Tasman Radiation Oncology Group (TROG) are the study Sponsor for Australia and New Zealand.

The Clinical Trials Research Centre (CTRC), part of the Liverpool Clinical Trials Collaborative at the University of Liverpool, is coordinating the study. The EORTC will receive your medical data and store this on their secure database.

Bangor University are part of the ROAM research team and will undertake a health economic analysis to see which treatment approach is most cost-effective. With your consent, Bangor University will receive routine hospital admissions data from NHS Digital via CTRC. We need this data to look at the likelihood of patients visiting or being admitted to hospital as a result of their atypical meningioma. The information we will be obtaining for everyone that participated in ROAM relates to hospitalisations for any reason and includes: the number of hospital visits or admissions, reason for admissions, length of stays and treatments received.

NHS Digital will also provide CTRC with information about study participants who may have passed away since the start of our study, including date and cause of death. We can access all of this through hospital records by securely sharing some of your personal details, specifically your name, date of birth and NHS number, with NHS Digital who then provides us with the information described above. Importantly, no other information that might identify participants will be shared with the ROAM research team and no identifiable patient data will be used in any publication or presentation. If you would like to discuss this or have any questions, please contact us.

The data we obtain will be stored at the CTRC, and used only for the purposes of the study by authorised personnel working on the trial or shared with authorised personnel working at NHS Digital.

If you prefer us not to access your information in this way, please let us know by opting out using the consent form. We will not share your information if you have already opted out. If you choose to opt-out after we share your information, we will destroy your data received from NHS Digital.

Additional funding has been provided by EORTC and TROG. This research has been approved by a research ethics committee, who are happy that the study is being conducted in an appropriate manner.

If you would like more information or have any questions about the ROAM trial, please talk to:

Principal Investigator: **<PI NAME>**

Research Nurse: **<RN NAME>**

Telephone: **<TELEPHONE NUMBER>**

THANK YOU FOR READING THIS INFORMATION SHEET.
WE HOPE YOU HAVE FOUND THIS SHEET HELPFUL

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<Trust/Site address 1>
<Trust/Site address 2>
<Trust/Site address 3>
<postcode>
Tel: <telephone number>

To be completed by the Researcher:

Centre Name:		NHS Number:	
Patient Initials:		DOB:	/ /
Randomisation number:	9 9 9 9 X X 9 9 9 9 9		

Adult Consent Form

		Please initial box
1.	I confirm that I have read and understand the information sheet dated **5th October 2017 (version 3.0)** for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
2.	I understand that participation is voluntary and that I am free to withdraw at any time, without giving a reason, and without my care or legal rights being affected.	
3.	I understand that my data will be retained for a minimum of 15 years at site/or at the Clinical Trials Research Centre (CTRC), part of the University of Liverpool, and that they will be stored in a confidential manner.	
4.	I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by authorised individuals from the research team and those listed under *additional information, regulatory authorities, sponsor or from the NHS Trust, where it is relevant to me taking part in this study. I give permission for these individuals to have access to my records.	
5.	I understand that my medical data will be collected for this study and may be used to develop new research and that data protection regulations will be observed.	
6.	I give permission for a copy of my consent form which will include my name, date of birth, postcode and NHS number to be sent to the CTRC (where it will be kept in a secure location), to allow confirmation that my consent was given.	
7.	I agree to medical personnel responsible for my welfare being informed of my participation in the study.	
8.	I agree to take part in the above study.	
9.	I understand that my GP will be notified about my participation in the ROAM trial.	

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To be completed by the Researcher:

Centre Name: NHS Number:

Patient Initials: DOB: / /

Randomisation number: 9 9 9 9 X X 9 9 9 9 9

For each of the questions below, you can decide to give your consent or not and still be part of the ROAM trial:	**Please initial box**	
	YES	**NO**
10. I agree for my data on NHS hospital admissions and treatment to be collected for the purpose of this study and understand this will include both routine paper and electronic NHS health care records covering the study period and a period of 6 months prior to the study for health economic analysis.		
11. I agree for my personal details which will include my name, date of birth, NHS number, postcode and gender to be shared with NHS Digital in order to receive hospital data (HES) for the purpose of the health economic analysis of the study.		
12. I agree to donate a tumour sample to the biobank and for this to be used in further research, including genetic testing, as described in the information sheet.		
13. I agree to blood samples, approximately 10mls, being collected for the biobank and for this to be used in further research, including genetic testing, as described in the information sheet.		
14. I agree that I may be contacted in the future in relation to this study or other related research.		

Name of Patient (please print)	Signature	Date
Name of person taking consent **(designated responsible person)**	Signature	Date

When completed, 3 copies need to be made: the original should be kept in the Investigator Site File, 1 copy for participant, 1 for the medical notes and 1 copy of the consent form only for CTRC, University of Liverpool (please send via fax)