MOSAICC

MyelOproliferative neoplasmS: An In-depth Case-Control STUDY

Study information booklet

Funded by:

MPN voice

LEUKAEMIA & LYMPHOMA NI

SCAN ME

PLEASE RETAIN THIS DOCUMENT

We invite you to take part in this important study which will help provide information on why people develop myleloproliferative neoplasms including polycythaemia vera (PV), essential thrombocythaemia (ET) and primary myelofibrosis (PMF). The study is being led by researchers at the University of Aberdeen along with researchers from Queen's University Belfast, University Hospital Southampton NHS Foundation Trust, University of Bristol, Curtin University (Australia) and University of Texas (USA). Hospitals across the UK are participating. The study is funded by MPN Voice and Leukaemia and Lymphoma, Northern Ireland.

What is the purpose of the study?

This is a study to identify what causes myeloproliferative neoplasms and the best way to improve patients' quality of life. To do this we would like to gather information and biological samples from you and from another person, of a similar age and sex as you, who does not have the disease. By comparing information from you (case) and the other person (control) we can learn a lot about myeloproliferative neoplasms. The data and biological samples collected will be stored confidentially and DNA/RNA extracted for the advancement of medical knowledge about myeloproliferative neoplasms. **Your responses will be treated confidentially and it will not be possible for anyone to identify you in any information produced from this study.**

What is involved?

Your clinician will provide information on your medical records to the study team and you can complete ALL or ANY of the following:

- Occupation/residence history calendar
- Telephone interview about your occupation, lifestyle and personal information
- Quality of life questionnaires
- Provide a 7.5ml blood sample (at your next appointment)
- Provide a saliva sample (complete at home and post to the study team)
- Provide some toe-nail clippings (to measure elements in your diet and exposures to environmental elements)

Why have I been chosen?

You have been chosen because you have been diagnosed with a myeloproliferative neoplasm (polycythaemia vera, essential thrombocythaemia or primary myelofibrosis) in the last 2 years. Patients attending clinics across the UK are being invited to take part in this research. We hope to talk to as many people as possible in order to come to reliable conclusions about the causes of myeloproliferative neoplasms and how to improve patients' quality of life.

What are the possible benefits of taking part?

There is no intended clinical benefit to you from taking part in the study. However, we hope that the information we get from this study will help improve our understanding about why some people get myeloproliferative neoplasms and how to improve quality of life for patients.

Who is organising and funding the research?

The research is being led by researchers at the University of Aberdeen. All study documentation has been reviewed by a Research Ethics committee (19/NI/0218). MPN Voice and Leukaemia and Lymphoma NI have provided funding to carry out the study.

What do I have to do now?

If you would like to participate, please sign the enclosed consent form agreeing to provide information and biological samples required for the study (you can choose any or all), the contact information sheet and occupation/residence history calendar (attached to the consent form) and post in the freepost envelope provided.

What will happen to me if I take part?

Once we have received your consent form and past occupations and residential history forms one of our team of trained researchers will contact you in order to arrange a convenient time to conduct a telephone interview. During the telephone interview, a researcher will use a questionnaire to ask you about; your lifestyle, your job (the occupation history form will help with this), your symptoms, your medical history, any history of cancer in your family, personal questions and a variety of questions on topics that previous research suggests may be related to myeloproliferative neoplasms. The telephone interview should take around 50 minutes to complete and will take no longer than 90 minutes.

At the start of the conversation you will be asked if you consent to having it recorded. You are not required to do so, but it will help us ensure that no important information is missed and will be used for quality control purposes. The information from the questionnaire will be used by the research team to explore factors that may be important in the development, early diagnosis and/or treatment of myeloproliferative neoplasms.

During this time we will post you a set of questionnaires to measure your quality of life along with a device to collect saliva (2ml) and a bag for the toenail clippings (if you have consented to provide these). Clear instructions on how to collect saliva and toenails will be provided and these can be done in the convenience of your own home. These samples and the questionnaires then need posted to us in the freepost packaging provided.

You will also be asked to donate a blood sample (7.5ml) taken at your next appointment. The saliva and blood samples will be stored in locked freezers at either the University of Aberdeen or Queen's University Belfast and used for future genetic analysis that will examine biological factors, including hereditary (genetic) factors, which may be important in the development, early diagnosis and/or treatment of myeloproliferative neoplasms. The toe-nail clippings will be used to tell us about your dietary and environmental exposures approximately one year ago. You may choose not to provide some or all of these samples and your medical care will not be affected in any way by the number or variety that you provide.

Your name, date of birth and postcode will be retained securely by the research team to link to healthcare datasets in the future to explore how the risk factors assessed in this study affect prognosis.

Some of the data and samples that you provide may be shared (pseudo-anonymously i.e. without your name or other identifiable information) and/or transferred abroad with collaborators from national and international (i.e. outside of the European Union) research institutions or with commercial companies for further research into myeloproliferative neoplasms.

Your help is also requested to identify a group of people without myeloproliferative neoplasms

In order to determine possible causes of myeloproliferative neoplasms, we need to compare your answers to those of people without the condition. In order to do so, if you participate in the study we would like to request that you give the enclosed envelope to a non-blood relative or friend who is the same sex as you and aged no more than 10 years older or younger. Please note that if you choose to take part in the study, you are under no obligation to invite a non-blood relative or friend to participate. Further details can be provided about this aspect of the study, when you are contacted by the researcher to arrange a suitable time for your interview.

Do I have to take part?

No - participation is voluntary. If you decide to take part you will be asked to keep this information sheet and to sign a consent form, contact information form and occupation/residence history calendar (enclosed) and return it in the stamped addressed envelope provided. You are free to withdraw from the study at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part in the study, will not affect the standard of care you receive. If you choose to withdraw from the study any information or samples provided before withdrawal will be retained.

What are the possible disadvantages and risks of taking part?

There are no major disadvantages of participating in the study. You are **not** being asked to take any additional medication and none of the standard treatment you receive will be affected by taking part.

What if something goes wrong?

This study does not involve the administration of any drugs or treatment procedures and therefore it is extremely unlikely that you will experience any harm as a result of taking part. However, the University of Aberdeen provides professional indemnity insurance against breach of professional duty by researchers and can be contacted on researchgovernance@abdn.ac.uk. In addition, you may use the complaints procedures operated by your local health trust if you have any concerns about the way you have been approached or treated during the course of this study. We can assist you with these procedures, should the need arise, but we will of course, make every effort to ensure that participation in the study will be an interesting and rewarding experience.

Will my taking part in this study be kept confidential?

The research has been reviewed and approved by Health & Social Care REC B (HSC REC B: 19/NI/0218). All information collected about you during the course of the research will be kept strictly confidential. However, if you indicate something of serious concern such as harm to yourself or others the researchers will contact your healthcare provider. Your personal identification details (i.e. name, date of birth and postcode) will be retained in a password protected file along with a unique identity number. This will be kept separate to the rest of the information you provide so that you cannot be recognised in any findings from the result. Instead, we will use a coding system to maintain your confidentiality.

If you agree to take part in the research your data will be stored by the research team. This data may also be looked at by officials from the University of Aberdeen and/or Queen's University Belfast to check that the study is being carried out correctly. Your GP will be notified of your participation in the research and will receive information about the study.

All data will be collected in accordance with the General Data Protection Act 2018. A privacy notice for this study can be accessed at:

https://www.abdn.ac.uk/about/privacy/research-participants-938.php

How will we use information about you?

We will need to use information from you and from your medical records for this research project. This information will include your:

- Initials
- NHS number
- Name
- Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to dpa@abdn.ac.uk or by ringing 01224 272596.

What will happen to the results of the research study?

The study will take at least three years to complete. The results will be presented at professional conferences and to local charitable groups (such as MPN Voice). We intend to publish the results in leading academic journals and other health publications. **Please note, you will not be identified in any publication or presentation.**

If you have any questions that have not been answered here, please contact us for further information.

The contact details for the study are provided below:

Aberdeen Centre for Health Data Science **University of Aberdeen** **Polwarth Building** **Foresterhill** **Aberdeen** **AB25 2ZD** **E-mail: mosaicc@abdn.ac.uk**	**Centre for Public Health** **Queen's University Belfast** **Institute of Clinical Sciences Block B** **Grosvenor Road** **Belfast** **BT12 6BJ** **E-mail: mosaicc@qub.ac.uk**

http://go.qub.ac.uk/MPN-MOSAICC

Thank you for taking the time to consider participating.

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