GLANZMANN'S 360

The Lived Experience of People with Glanzmann's Thrombasthenia

PARTICIPANT INFORMATION SHEET

Study Title:	Glanzmann's 360 – The Lived Experience of People with Glanzmann's Thrombasthenia
Study Sponsor:	Haemnet
Protocol Number:	Version 1.1
Principal Investigator:	Simon Fletcher
Co-Investigators:	Dr Kate Khair, Kathryn Jenner, Michelle Huet

Introduction

We would like to invite you to take part in our research study on the experience and impact of living with Glanzmann's Thrombasthenia. Before you decide whether you would like to participate, it is important that you understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully, and please ask us if there is anything that is not clear or if you would like more information. Our contact details are provided at the end of this information sheet.

What is the purpose of the study?

The purpose of this study is to understand the impact of living with Glanzmann's Thrombasthenia on individuals and their families. We also want to discover how happy you are with treatment and to see if you have unmet needs related to your Glanzmann's Thrombasthenia.

Why have I been invited?

You have been invited to participate in this study because you have Glanzmann's Thrombasthenia and because you participated in the on-line survey about Glanzmann's Thrombasthenia.

Do I have to take part?

No, your participation in this study is entirely voluntary.

You can choose not to take part, or if you decide at a later stage that you would rather not participate in the study, you can withdraw at any time without providing a reason. Withdrawing from the study will not affect your care in any way. If you decide to take part in this study, you will be asked to sign a consent form. You will be given a copy of the consent form to keep along with this information sheet.

What will happen to me if I take part?

1) We will ask you to do a face-to-face interview with one of the research team (listed above). The interview is expected to last around one hour. If you agree to participate in the study, the research team will contact you to organise a mutually convenient time and place for the interview. The interview can be undertaken at the hospital, your home or other another mutually convenient site, or over the internet using a video conferencing platform. During the interview, notes will be taken, and the conversation will be digitally recorded. After the interview, the audio recording will be transcribed and analysed by the study research team.
2) To confirm your diagnosis of Glanzmann's Thrombasthenia we will ask you to show us a National Haemophilia Database Registration card, or a hospital letter about you. We will NOT take copies of these.
3) We will give you a unique study number that is known only to you and the study team.

How will we use information about you?

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

- name (known only to the research team)
- age
- sex
- contact details
- previous bleeding history and treatment

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 study code number instead.

We will keep all information about you safe and secure.

We will write study reports in a way that no one can work out that you took part in the study.

What are my choices about how my information is used?

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

Where can I find out more about how my 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 simon.fletcher@ouh.nhs.uk, or kate@haemnet.com or
- by phoning us on 01865 572046
- by contacting our data protection officer mike@haemnet.com

What are the possible benefits of taking part?
There are no direct benefits to you as a participant. However, it may help others in the future.

What are the possible disadvantages and risks of taking part?
Taking part in the interview will require giving up some of your time.

Although we do not think that answering the questions during the interview will be distressing, psychological support can be arranged for you if required. This could be via your GP or through your treatment centre, who will be informed of your participation.

What will happen if I change my mind about participating in the study?
Your participation is entirely voluntary. You are free to withdraw from the study at any time, without giving any reason, and without your care or legal rights being affected. If you decide to withdraw your consent to participate in this study, no additional information about you will be collected. All the data and information collected up to the point of withdrawal will be kept as outlined below and will be used in the study.

Who is sponsoring and funding the study?
The study is sponsored by Haemnet. Haemnet is a UK based research consultancy that supports health and social care professionals to ensure that excellent care becomes an everyday experience for people with bleeding disorders.

The overall study is funded by Hemab Therapeutics. Hemab Therapeutics are a biotechnology company developing next-generation treatment for bleeding and clotting disorders. Hemab are developing HMB-001, a novel potential for Glanzmann Thrombasthenia and other rare bleeding disorders. Hemab Therapeutics will not have access to any of your personal data but will receive a final report that may use anonymised quotes from interviews.

Will I be reimbursed for taking part?
You will receive a thank you gift voucher for participating (this will be £100 per individual) following completion of the interview. We will also reimburse travel expenses if these are incurred.

Will my taking part in this study be kept confidential?
All information collected about you in the course of the study will be kept strictly confidential. No personal identifiable information, such as your name and address, will be included in these records.

- Participant information sheets with study code numbers will be kept in a locked cabinet in a secure research office at Oxford Haemophilia and Thrombosis Centre. These will be kept for 12 months following the end of the study, after which they will be shredded.
- Paper records produced in the course of the study, including transcripts of audio recordings, will be kept in locked cupboards by Haemnet. These will be kept for 15 years after the study, after which they will be shredded.
- Audio recordings will be held securely in electronic format by Haemnet. All audio recordings will be deleted once the study has been analysed. This will be within 24 months of the study start date.
- Any data held on computers, including audio recordings, will be password protected in line with NHS data protection procedures.
- All audio recordings will be transcribed word for word by a professional transcription service unknown to you. The transcriptionist will be required to sign a confidentiality agreement.

Who has reviewed the study?
This research programme has been reviewed by the Proportionate Review REC Committee. The reference number is 22/PR/0373.

What happens if there is a problem?
We would not expect you to suffer any serious harm or injury by participating in this study. If you are harmed by taking part in this study, there is no special compensation arrangement. If you are harmed due to someone's negligence then you may have grounds for legal action, but you may have to pay your legal costs. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of the consent process or the study, the National Health Service Complaints mechanism is available to you. If you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint, please contact the Patient Advice and Liaison Service (PALS) at the Oxford University Hospitals NHS Foundation Trust (phone: 01865 235855; email: PALS@ouh.nhs.uk).

Will I be informed of the results of the study?
This study will be reported in both specialist bleeding disorder publications and at international conferences. You will receive a final report from the study team.

Who should I contact for further information?
You may discuss the study with the principal investigator or a member of the research team by calling or emailing:

Simon Fletcher: 01865 225316 or simon.fletcher@ouh.nhs.uk
Dr Kate Khair: 07515 900812 or kate@haemnet.com

Future studies about Glanzmann's Thrombasthenia

This study is part of a group of planned studies about living with Glanzmann's Thrombasthenia. We would like to be able to contact you in the future, to see if you are interested in participating in any new studies. We have asked (on the consent form) for you to agree that Haemnet can keep your contact details until 31/12/2027 to be able to contact you again in the future.

If you are happy and agree to this, Haemnet will contact you again in the future to seek new consent from you for new studies, which may involve sharing your data with Hemab who are the funding company behind this study. We will only do this with your agreement and written consent(s).

Thank you for taking the time to read this information sheet