Randomised controlled trial of EArly transjugular intrahepatiC porTosystemic stent-shunt in Acute Variceal Bleeding REACT-AVB trial.

SUMMARY PATIENT INFORMATION SHEET

We would like to invite you to participate in the REACT-AVB trial.

This Information Sheet summarises the purpose of the trial and what is involved in taking part. Please note: participation is voluntary and this will not affect the care that you receive.

Trial Summary

- Variceal bleeding is a serious complication of liver cirrhosis.
- Patients with variceal bleeding need treatment with medicines and endoscopic treatment to stop the bleeding and prevent further bleeding. This is known as standard of care (SOC).
- For patients at high risk of bleeding again, an "early" Transjugular Intrahepatic Portosystemic Stent-Shunt (TIPSS) is offered to reduce the risk of further bleeding.
- We do not know which treatment is better. Therefore, this trial is being conducted to find out if early TIPSS is better than SOC.
- This trial will randomly assign patients to either SOC or early TIPSS.
- You will be seen, either as an inpatient, during standard clinic visits or over telephone/video consultation, every few months to assess well-being, look for any untoward effects and collate further data needed for this trial.
- Trial participation and information provided will be kept confidential and handled in accordance with General Data Protection Regulation (GDPR) and Data Protection Act 2018 for health and care research.
- You will be provided with the main patient information sheet when you feel well enough.
- In order to take part in the trial, you will be required to sign a consent form.
- We aim to improve the care of patients with liver cirrhosis and oesophageal variceal bleeding. **If we conclude that early TIPSS is more effective in terms of survival, cost, and quality of life than SOC, this could lead to a major change in clinical practice.**