

<TO BE PRINTED ON TRUST HEADED PAPER>



Timing Of Nutrition In emergency laparotomy

UNIVERSITY OF
BIRMINGHAM



Birmingham Clinical Trials Unit

Summary Participant Information Sheet

A randomised trial comparing early parenteral nutrition vs standard nutritional care in adults undergoing emergency laparotomy.

Version 2.0 07-Jan-2026

We would like to invite you to participate in the **TONIC trial.**

This Information Sheet summarises the purpose of the trial and what is involved in taking part.

Please note that this is an abbreviated version of our information sheet and that when you feel well or if you have further questions you can refer to the standard version.

In order to take part in the trial, you will be required to sign a consent form.

What is the TONIC trial?

The TONIC Trial is a research study looking at the best way to support nutrition in adults who need emergency abdominal surgery. After such surgery, the gut often stops working temporarily, making it hard to eat or drink. This trial compares two approaches:

- **Early Parenteral Nutrition (PN):** Giving nutrition directly into the bloodstream within 48 hours of surgery.
- **Usual Nutritional Care:** Waiting until the gut starts working before feeding, unless it hasn't recovered by day five.

Why is the research being done?

Doctors know that patients who go without food for several days after surgery are more likely to have complications. However, it's unclear whether starting nutrition early through a drip helps reduce these risks or causes other problems. This trial aims to find out which approach leads to better recovery.

Why have I been invited?

You've been invited because you need emergency abdominal surgery. Participation is entirely voluntary. Saying no will not affect your care in any way.

What happens if I take part?

If you agree,

- You'll be randomly assigned to one of two groups:
 - **Early PN group:** Nutrition via a central line within 48 hours post-surgery. If you're in the PN group, a special line will be placed in your vein to deliver nutrition. This will be done safely, and monitored with blood tests and a chest x-ray.
 - **Usual care group:** Nutrition support as per current practice, with PN considered only if gut function hasn't returned by day 5. If you're in the usual care group, your doctors will decide when and how to feed you based on your recovery.

What will we monitor?

- Your recovery in hospital including any complications.
- Your ability to eat and drink, and when your gut starts working.
- Your quality of life and physical recovery, including a short sit-to-stand test and questionnaires at discharge.
- We'll follow up with you at 30 and 90 days after surgery.
- Data will be collected on your medical history, surgery, recovery, and quality of life.

What are the benefits and risks:

- **Benefits:** You may not benefit directly, but your participation will help improve care for future patients undergoing emergency surgery. Some people find the extra monitoring and questionnaires helpful.
- **Risks:** PN is generally safe, but as with any treatment there are some risks. PN may cause changes in blood salts, high blood sugar, liver test changes, infection (rare) or refeeding syndrome. These are monitored and managed by the care team.

Confidentiality - Will my information be kept private?

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study, we will save some of the data in case we need to check it AND for future research.

We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

The research team will seek consent at a suitable time from the participant, prior to the commencement of the PN where clinically appropriate.

Can I change my mind?

Yes. You can withdraw at any time without giving a reason. Already collected data will still be used.

Will any cost be covered?

To thank you for your time and to help cover any travel expenses that may be incurred, you will receive a fixed price reimbursement of £35, in the form of a voucher, for attending each of the trial visits on Day 30 and Day 90 whether that be in person or remotely. This amount is intended to compensate for both your time and any travel costs incurred; no additional reimbursements will be offered. Reimbursement will be provided after each visit and once the questionnaires have been completed. You will receive a high street gift voucher to the value of £35. This will be sent to you directly by the University of Birmingham Trials Office either via e-mail or post depending on your preference.

Who is running the trial?

The trial is sponsored by the University of Birmingham and managed by the Birmingham Clinical Trials Unit. It is funded by the National Institute for Health and Care Research (NIHR). The trial has been reviewed and approved by a Research Ethics Committee.

Where can I get further information?

This is an abbreviated version of our standard patient information sheet. Please refer to that when you feel well enough to do so.

Should you require further information or would like to speak to someone about the **TONIC** trial, or proceed to join the **TONIC** trial, please contact a member of your local research team:

Name:	
Job Title:	
Contact Details:	

Alternatively, you can contact the TONIC trial team: tonic@trials.bham.ac.uk

This infographic provides a visual overview of the steps and activities involved in taking part in the TONIC trial

