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Timing of nutrition in emergency laparotomy

Submission date
28/01/2026

Recruitment status
Not yet recruiting

Registration date
30/01/2026

Overall study status
Ongoing

Last Edited
30/01/2026

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many people who need emergency abdominal surgery (called an emergency laparotomy or laparoscopy) are unwell and may not be able to eat normally for some time after their operation. Good nutrition is important for recovery, but there is uncertainty about the best time to start nutrition given directly into a vein (called parenteral nutrition). This study aims to find out whether starting parenteral nutrition early, within the first two days after emergency surgery, reduces complications in hospital compared with usual nutritional care. The study is called Timing of Nutrition in Emergency Laparotomy (TONIC).

Who can participate?
Adults aged 18 years or older who are having urgent or emergency abdominal surgery as part of standard NHS emergency care may be able to take part. People cannot take part if their surgery is for major trauma, if they are receiving endoflife or palliative care, if they have had abdominal surgery in the previous 30 days, or if they were already receiving longterm parenteral nutrition before coming into hospital.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will receive parenteral nutrition started within 48 hours of their emergency operation. The other group will receive usual nutritional care, which may include normal food, oral nutritional supplements, tube feeding, or no extra nutrition at first; parenteral nutrition in this group would usually not start until at least five days after surgery if needed. Information about recovery, complications, length of hospital stay, and quality of life will be collected from medical records and from short questionnaires up to 90 days after the operation.

What are the possible benefits and risks of participating?
Participants may or may not benefit directly from taking part. Early parenteral nutrition might help some people recover with fewer complications, but this is not yet known, which is why the study is being done. Risks are similar to those of standard care and may include problems related to feeding through a vein, such as infection or irritation at the line site. All participants will be closely monitored, and their usual medical care will not be affected by taking part in the study.

Where is the study run from?
The study is run from the Birmingham Clinical Trials Unit at the University of Birmingham and is

taking place in around 25 NHS hospitals across England, Scotland, and Wales that provide emergency surgical care.

When is the study starting and how long is it expected to run for?
The first participants are expected to join the study in March 2026. Recruitment is planned to continue until August 2027, and the study is expected to finish in February 2028.

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR), a UK government research funding organisation. The sponsor of the study is the University of Birmingham.

Who is the main contact?
The main public contact for the study is the TONIC Trial Office at the Birmingham Clinical Trials Unit. The contact person is Miss Georgia Mitchell, and the study team can be contacted by email at tonic@trials.bham.ac.uk.

Contact information

Type(s)
Public

Contact name
Miss Georgia Mitchell

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Additional identifiers

Integrated Research Application System (IRAS)
328678 (England/Wales)

Integrated Research Application System (IRAS)
365916 (Scotland)

Study information

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

Acronym
TONIC

Study objectives
The primary clinical objective is to determine whether early parenteral nutrition (PN) in patients undergoing emergency laparotomy/laparoscopy reduces in hospital complications as compared to usual nutritional care.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 14/01/2026, East of England - Essex Research Ethics Committee (2 Redman Place, London, EC20 1JQ, United Kingdom; +44 207 1048106; essex.rec@hra.nhs.uk), ref: 25/EE/0268

2. submitted 20/11/2025, Scotland A (272 Bath Street, Glasgow, G2 4JR, United Kingdom; +44 7814609032; manx.neill@nhslothian.scot.nhs.uk), ref: 26/SS/0001

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Hospital complications in adults undergoing emergency laparotomy

Interventions
Early PN through central venous catheter (CVC) or PICC, commencing within 48 hours of emergency laparotomy/laparoscopy, with biochemistry monitoring as per NICE Clinical Guideline 32. PN is prescribed on a 24-hour basis and would continue until the participant has recovered gastrointestinal function, sufficient to allow adequate enteral intake. This is determined by the nutrition team in collaboration with the surgical team.

Standard nutritional care, which may include no support, oral nutritional supplements or nasoenteric feeding at anytime point. Clinicians can use PN in the control group, but, as per NICE guidance, not before 5 days post-surgery unless there is pressing clinical need.

Participants will be followed up at discharge, 30 days and 90 days post operation.

Randomisation will be provided by BCTU using a secure online Electronic Data Capture (EDC) system (available at https://bctu-redcap.bham.ac.uk/). After eligibility has been confirmed and informed consent (or declaration for those who cannot provide informed consent) has been received, the participant can be randomised into the trial using the online EDC system. A worksheet replicating the electronic randomisation form and the eligibility and consent form may be used to collate the necessary information prior to randomisation. All questions and data items on the online Randomisation Form and the eligibility and consent form must be answered prior to a potential participant being randomised into the trial and a Trial Number being issued.

Participants will be randomised at the level of the individual in a 1:1 ratio to either early administration of PN or standard care via a central secure web-based randomisation system available 24 hours/day at the BCTU. A minimisation algorithm will be used within the randomisation system to ensure balance in the intervention allocations over the following variables:
NELA risk (<5 OR ≥5%) [33]
Nutrition Risk Score (<3 OR ≥3) [34]
Recruiting site (hospital name).

This is an unblinded trial. It is not possible to blind participants or clinicians due to the interventions being used. It is not possible to blind outcome assessors as some outcomes are related to the delivery of the intervention.
Following randomisation, a confirmatory e-mail will be sent to the local PI, person randomising and nominated site contacts. The confirmatory email will also be sent to the TONIC Trial mailbox.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. In-hospital complications assessed at point of hospital discharge measured using Comprehensive Complication Index (CCI) at Discharge, 30 and 90 days after operation

Key secondary outcome(s))
1. Number and severity of complications at 30 and 90 days post-operation measured using Comprehensive Complication Index (CCI) at 30 and 90 days after operation

2. Number and severity of complications (respiratory, cardiovascular, surgical site infection (SSI), reoperation), including mortality. measured using Clavien Dindo Classification (CDC) at 30 and 90 days after operation

3. Functional assessment measured using Sit to stand test at Discharge

4. Number and severity of infectious complications (SSI, vascular line infection, hospital acquired pneumonia, urinary tract infection, all defined according to the CDC), assessed in hospital, prior to discharge measured using CDC at Discharge

5. Length of post-operative hospital stay (in nights following operation) measured using patient records at Discharge

6. Assess the impact of early PN on unplanned readmissions following discharge up to 90 days after operation measured using patient records at 30 days and 90 days after date of operation

7. Discharge destination (usual residence, residential, or nursing home) measured using patient records at Discharge

8. Use and duration of PN and total calories administered post-operatively, recorded for each arm at discharge measured using Use of parenteral nutrition (yes/no), duration of PN (number of postoperative days), and total caloric intake (kilocalories) administered postoperatively, recorded for each study arm at the point of discharge using medication and nutrition records at Discharge

9. Use of other nutritional interventions (Oral Nutritional Supplements), recorded for each arm prior to discharge measured using Use of oral nutritional supplements (yes/no), recorded for each study arm prior to discharge using medication and nutrition records at Discharge

10. Process metrics: Time from randomisation to line insertion (hours); Time from operation to starting PN (hours) measured using patient records at discharge

11. Function (including activities of daily living) measured using Barthel index of function at discharge, 30 and 90 days post-operation

Completion date
29/02/2028

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Scheduled for NELA eligible expedited, urgent or immediate emergency laparotomy or

laparoscopy according to National Confidential Enquiry into Patient Outcome and Death (NCEPOD) criteria
3. Able to give informed consent, with interpreters where necessary OR personal consultee /legal representative provides assent/consent if a patient temporarily lacks capacity

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Undergoing trauma-related laparotomy or laparoscopy
2. Being treated with palliative/end of life intent
3. Abdominal surgery in the preceding 30 days
4. On long term PN prior to admission

Date of first enrolment
16/03/2026

Date of final enrolment
31/08/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital

Mindelsohn Way
Edgbaston
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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	13/11/2025	29/01/2026	No	No