

When to randomise?

Randomise infants as soon as possible after consent. Ensure:

- Eligibility has been confirmed by a delegated medical doctor
- Eligibility has been documented in the infant's medical records
- Written informed consent form has been completed

Who can randomise?

Randomisation can be completed by a member of staff who has completed **ALL** of the following:

- Watched the TOAST randomisation training video
- Has been authorised to undertake randomisation by the Principal Investigator on the Delegation Log
- Has received username and password for the Randomisation Website from the TOAST Study Team (request by emailing toast@npeu.ox.ac.uk)

Where to find randomisation website?

- From a device with internet access, visit <https://rct.npeu.ox.ac.uk>
- Select the 'TOAST' icon
- Enter username and password using your assigned login details

How to randomise?

Randomisation Program

If you need to contact us **urgently** with randomisation problems, please click on this [link](#)

Logged in as: **research nurse-alpha** [Evelina London Children's Hospital]

Someprazole: 6 packs available (6 in NNU)
Omeprazole: 6 packs available (6 in NNU)

Menu

Latest 3 participants		
Study no	Date randomised	Time since randomisation
3564	27/11/25 17:39	about a week
3556	27/11/25 16:35	about a week
3542	27/11/25 16:24	about a week

Please select one of the following options:

- 1. Randomise infant**
- Randomise infant with random data
- Recruitment list (69)
- Login packs at NNU
- Allocate another pack
- Current packs
- Pack summary
- Pack list
- Pack list (detailed)
- Add infant to screening log

Once you have logged in, select 'Randomise infant'

Randomisation Program

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Logged in as: **research nurse-alpha** [Evelina London Children's Hospital]

Section 1: Eligibility

Time of randomisation: 12 Dec 2025 10:15

1 error found - please amend entry

Infant details

1.1. What is the infant's date of birth? / / Age: 1d

1.2. What is the infant's EDD (expected date of delivery)? / / Gest age at birth: 41*6

Inclusion criteria

1.3. Has the infant been diagnosed with oesophageal atresia with distal tracheo-oesophageal fistula?

Answer must be Yes to continue

1.4. Has the infant undergone ligation of the fistula and oesophageal anastomosis at the same time during the first operative intervention?

1.4.1. What was the date of this surgery? / /

Complete the infant details and inclusion/exclusion questions to confirm the infant's eligibility for TOAST.

If any of the criteria show that the infant is not eligible, this will be flagged as a red error, and it will not be possible to randomise the infant.

Please sign off this form once complete

Surname

Forename

Professional email

Enter YOUR name and email address at the bottom of the page to sign off the form.

Select 'Continue' when complete.

Randomisation Program

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Logged in as: **research nurse-alpha** [Evelina London Children's Hospital]

Section 1: Eligibility

Time of randomisation: 12 Dec 2025 10:15

Press **Complete** to confirm randomisation or **Amend** to change any values

Infant details

1.1. What is the infant's date of birth? / /

1.2. What is the infant's EDD (expected date of delivery)? / /

Inclusion criteria

1.3. Has the infant been diagnosed with oesophageal atresia with distal tracheo-oesophageal fistula?

1.4. Has the infant undergone ligation of the fistula and oesophageal anastomosis at the same time during the first operative intervention?

1.4.1. What was the date of this surgery? / /

1.5. Does the infant have written informed consent obtained from an individual with parental responsibility?

1.6. Is the infant expected to survive beyond the first year of life?

A confirmation page will appear. Review the information you have entered. If you would like to make any changes, click 'Amend' to go back to the editable form.

To cancel the randomisation, click 'Cancel' to return to the homepage.

Click 'Complete' to randomise the infant.

Randomisation Program

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Section B: Randomisation

TOAST study number:
3625

Pack ID (IV - esomeprazole):
A1207

Pack ID (Enteral - omeprazole):
R1445

Please record the study number (**3625**) and pack IDs (**A1207** and **R1445**)

Please press the **Print** button below to generate a pdf which should be printed.

Print

Enter contact details

Thank you for entering this infant into the TOAST study.
Please click the link below to log out

[Log out](#)

[Home](#)

The website will issue a Study Number and two Pack IDs – one each for IV and enteral administration.

Click 'Print' to generate a PDF of the data entered at randomisation and the Pack IDs. File a copy of this PDF in the infant's medical records. Ensure that Pack IDs are recorded on the Daily Dosing Log. Add the Study Number to the top of the infant's Consent form.

Click 'Enter Contact Details' to go to the infant's Contact Details Form as soon as they are randomised.

Contact Details

Please enter the **Contact Details** information as soon as possible – this is essential for trial processes to take place.

If you are unable to complete the contact details section immediately following randomisation, please return to the website as soon as possible to complete it. From the randomisation Menu, click on the 'Recruitment list' link, then click 'Edit' in the 'Edit contact details column' for the participant whose contact details you wish to edit.

Randomisation Program

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Evelina London Children's Hospital

Study no	Time randomised	Pack (IV)	Pack (Enteral)	Print	Edit contact details
3611	11/12/25 12:05	A1269	R1437	Print	Edit
3564	27/11/25 17:39	A1271	R1467	Print	Edit
3556	27/11/25 16:35	A1300	R1492	Print	Edit

This takes you to the Contact Details form:

Infant's details

DOB: 10/12/2025

Forename unknown Surname NHS Number

Consent for infant

Which parent consented for the infant? Mother Father Other

Details of parent consenting for the infant:

Forename Surname Mobile number Address

Landline number

Email Postcode

In the contact details section you will be asked for the following:

- Infant's name and NHS number
- Who consented for the infant and their name and contact details
- Whether the mother consented to complete maternal questionnaires, and her details (including a mobile and/or email) if she is not the consenting parent
- How the parents will report adherence and complete follow-up questionnaires
- Any potential communication barriers with the parents
- Infant's GP and local hospitals: please include details for the hospital from which the infant was referred and/or may present to in an emergency

Even if you do not have all of this information immediately, please complete what you do have and fill in the rest later.

Key points

1. If you have not yet confirmed whether the mother consents to complete maternal questionnaires (i.e. if she is unavailable), record this as "Not yet" on the Contact details form.

Consent for mother

Has the mother consented to Question 10 on the consent form?
(*I agree to complete the questionnaires specified for the mother?)

Yes Not yet (is currently unavailable) No

Please update this to 'Yes' or 'No' as soon as you are able.
The Baseline Questionnaire will not be sent out (as a link via email or mobile) **until the mother's consent has been recorded as 'Yes'**.

2. The mother will be the main contact (questionnaires will be sent to her and the TOAST app account will be linked to her email address), unless the mother both did not provide consent to complete the maternal questionnaires **and** was not the consenting parent.
3. If the mother does not consent to complete maternal questionnaires: please advise that she does not need to complete the final section in the 6m/12m/18m/24m parent questionnaires. The 3m and 9m parent questionnaires do not include a maternal component so can be completed in full.
4. We recommend that you confirm whether the mother gives consent before setting up the TOAST app, as the TOAST app can only be linked to one email address.
5. The Contact Details form includes a space to record the date on which the parent is trained on reporting adherence.

<p>A few days before the infant is due to be discharged home, please provide training to the parent on reporting adherence via app / online form / paper diary.</p> <p>A date must be entered in order to allow the parent(s) using the app or online form to start logging adherence records.</p>	<p>Date of training on adherence reporting</p> <input type="text"/>
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Please ensure that, a few days before the infant is due to be discharged home, you discuss reporting of adherence with the parent/carer(s) and fill in the date of this discussion. **Parents cannot start logging adherence records on the TOAST app/online until this date has been provided.**

TOAST Medication

Once the infant has been randomised, they will need to be prescribed their TOAST medication as soon as possible (please refer to **TOAST Guidance Sheet 7: IMP**).

Data Entry

Once the infant has been randomised, please ensure completion of the Entry Form on OpenClinica (please refer to **TOAST Guidance Sheet 8: CRFs**).

Cot Card

Wipe-clean TOAST Cot Cards are included in the TOAST Document Box for display on the infant's cot to ensure awareness of the infant's participation in the TOAST Study.