

## Screening

All newborn infants with oesophageal atresia (OA) and distal tracheo-oesophageal fistula (TOF) should be identified as potential participants by their clinical care team. Anyone involved in the TOAST Study can support identification of these infants.

## Antenatal Approach

Where an infant has an antenatal diagnosis of OA, parents can be given information about TOAST, but confirmation of eligibility and consent must be taken after the infant's first operative intervention (see eligibility criteria).

## Eligibility

Eligibility must be confirmed by a medical doctor who is authorised on the TOAST Delegation Log before consent is taken from the parent(s)/carer(s). All infants screened for eligibility should be entered onto the TOAST Screening Log.

The eligibility criteria are as follows:

### Inclusion Criteria

- Infants (of any sex and any gestational age) with OA with distal TOF who have undergone ligation of the fistula and oesophageal anastomosis at the same time during the first operative intervention
- Infants have written informed consent obtained from an individual with parental responsibility
- Infants are expected to survive beyond the first year of life
- Infants within the end of day 3 after surgery (where day of surgery is day 0)
- Infants up to 2 weeks postnatal age
- In the opinion of a clinical member of the local research team, parents(s)/carer(s) of the infant are able and willing to comply with all trial requirements, (including having a good understanding of the English language), or can be supported to do so (including the use of translation services).

### Exclusion Criteria

- Infants with OA without distal TOF
- Infants who have undergone an operative intervention (e.g. emergency tracheo-oesophageal fistula ligation without anastomosis, initial gastrostomy) prior to the one where they underwent oesophageal anastomosis
- Infants with any additional significant disorder or disease that, in the opinion of the responsible paediatric surgeon or neonatologist, makes entry into the trial inappropriate
- Infants taking any medication that, in the opinion of a clinical member of the local research team, makes entry into the trial inappropriate

## Co-recruitment

Co-recruitment to other research studies must be agreed by the Chief Investigator(s). Studies that have been reviewed already can be found at [www.npeu.ox.ac.uk/toast/clinicians/faqs](http://www.npeu.ox.ac.uk/toast/clinicians/faqs). For all other studies please contact the TOAST Study team prior to consent via email [toast@npeu.ox.ac.uk](mailto:toast@npeu.ox.ac.uk) or phone 01865 289278.

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## Screening Log

Paper copies of the TOAST Screening Log can be found in your TOAST Document Box. An electronic version of the document is located in the electronic Investigators Site File (eISF), should you require more copies. Paper Screening Logs are provided for internal use only, and do not need to be submitted back to the TOAST Study team, unless requested for additional monitoring purposes. You can store your paper Screening Logs in the TOAST site folder provided.

## Summary Screening Log

All aggregate data from the paper Screening Log should be regularly entered into the anonymised Summary Screening Log on the TOAST Randomisation website. Infants who are randomised are entered onto the Summary Screening Log automatically. Site staff who delegated for 'Screening' and 'Randomisation' responsibilities on the TOAST Delegation Log may enter information onto the Summary Screening Log. Where possible, please include a reason why an eligible infant was missed.

Please ensure that patient identifiable data is NOT included in the Summary Screening Log, for example the infant's name or NHS number. Infants can be allocated your own ID number for the purposes of screening, such as 001, 002 etc.

Please update the Summary Screening Log at least once per month – you will be sent email reminders.

You can access the TOAST Randomisation website at: <https://rct.npeu.ox.ac.uk/toast> and login using your assigned individual login details (please refer to **TOAST Guidance Sheet 5: Randomisation**).

**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] Site: **Evelina London Children's Hospital**

Esomeprazole: 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**
2. **Randomise infant with random data**
3. **Recruitment list (69)**
3. **Login packs at NNU**
4. **Allocate another pack**
5. **Current packs**
6. **Pack summary**
7. **Pack list**
8. **Pack list (detailed)**
9. **Add infant to screening log**
10. **Screening log**
11. **Screening log - print**
12. **Screening log - download**

Update the Summary Screening Log by clicking on the 'Add infant to screening log' link.

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