

Randomisation should occur as soon as possible after consent is obtained. This is to ensure that infants do not become ineligible before they are randomised. Please ensure site staff and parents are aware of the date after which the infant can no longer be enrolled in the study.

Prior to randomisation, please ensure:

- Written informed consent has been obtained using the DOLFIN Consent Form (see **Guidance Sheet 2 – In-person and Remote Informed Consent**).
- Eligibility has been **confirmed by a delegated individual as recorded on the DOLFIN Site Delegation Log** (see **Guidance Sheet 1 – Screening and Eligibility**).

Randomisation will use a 1:1 allocation ratio to either:

- (1) Treatment supplement: Micronutrient breast milk/formula milk/food supplement containing a nutrient blend of LCPUFAs, choline, UMP, and CMP.

Or

- (2) Matched control supplement, containing fractions of the active components in the investigational product and no UMP or CMP.

Note: higher order births e.g. twins or triplets will be allocated to the same arm.

Randomising infants to DOLFIN

Randomisation of infants is managed via a secure web-based randomisation webpage hosted by the National Perinatal Epidemiology Unit Clinical Trials Unit (University of Oxford) with telephone backup available at all times (365 days per year). Training will be provided to sites as required.

- To randomise an infant to DOLFIN, access the online randomisation website at: <https://rct.npeu.ox.ac.uk/> or via the 'Randomise to DOLFIN button' on the study website <https://www.npeu.ox.ac.uk/dolfin>.
- Log into the randomisation website using the centre login details (located in DOLFIN Document Box and eISF).
- Select centre name from the drop-down list.
- Enter username and password (single centre login details for all staff).

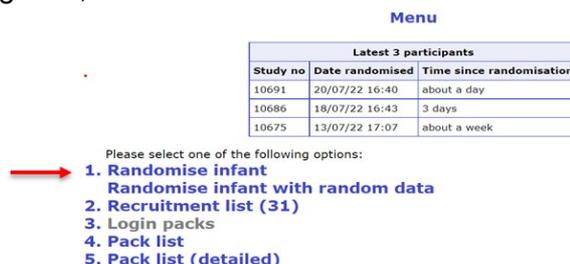
Once you are logged in, click "Randomise infant":

Menu

Latest 3 participants		
Study no	Date randomised	Time since randomisation
10691	20/07/22 16:40	about a day
10686	18/07/22 16:43	3 days
10675	13/07/22 17:07	about a week

Please select one of the following options:

1. **Randomise infant**
2. **Recruitment list (31)**
3. Login packs
4. Pack list
5. Pack list (detailed)



Once the form has been completed, click "Continue".

If you have inputted any data that suggests the infant is ineligible, this will be flagged up and you will not be able to proceed any further. If unsure about eligibility please discuss with the local PI, and if required the DOLFIN study team, before randomising the infant.

On the next screen, check that the data inputted is correct. If any information is incorrect, click “Amend” and enter the corrected information before clicking “Complete”.

Section A: Eligibility

Time of randomisation: 2 Nov 2023 14:22

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

Complete **Amend** **Cancel**

Section A: Infant details

A1. What is the infant's date and time of birth? / /
 : 24hr clock

A2. Expected date of delivery (EDD – by maternal scan if available, if not LMP) / /

A3. What is the infant's sex?

A4. What is the infant's current weight (g)?

A5. Is this infant one of a multiple pregnancy?

A6. Is this infant currently an inpatient?

Inclusion criteria

A7.1. Has written informed parental consent been obtained from an individual with parental responsibility?

A7.1.1 Who signed the consent form?

A7.1.2 Please enter name of person who obtained consent

On the confirmation screen, the infant will be allocated a DOLFIN Study ID. Enter the DOLFIN Study ID immediately onto the completed **DOLFIN Consent Form** (see **Guidance Sheet 2 – In person and Remote Informed Consent**)

Each infant will be allocated a treatment pack with an ID number during randomisation. This number will correspond to a pack containing 100 sachets of either the treatment supplement or control supplement. Enter the treatment pack ID onto the infant's **DOLFIN Dosing Log**.

Demonstration version only

Randomisation Program

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

Logged in as: **Centre 1 (City 1)**

Section B: Randomisation

DOLFIN study number:
10706

Treatment pack ID:
Z1117

Please record the study number **10706** and treatment pack ID **(Z1117)**

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

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

[Log out](#)

Click “Print” and save a copy of the resulting PDF in the electronic Investigator Site File (e-ISF).

This project was funded by the National Institute for Health and Care Research Health Technology Assessment (HTA) Programme. (Project number NIHR 130925).

Technical support

If you experience technical difficulties or require technical support, please contact the DOLFIN study team using the contact details below:

- During office hours, contact the DOLFIN study team on: 01865 617919
- In the case of urgent out-of-hours queries, please phone 0800 1385 451

If you have tried to randomise an infant and are not sure if it has been successful, return to the home screen of the randomisation website. This will list the most recent randomisations at your site. Please check this before trying to randomise the infant again (to prevent duplicate randomisations).

Contact Details Form

After an infant has been randomised, click the “Enter contact details” button. This will open up a new window to enter contact details as required.

- It is important to record the infant and mother’s healthcare number (e.g. NHS number). This is for data linkage.
- Please enter parent contact details (email address, mobile number and postal address) at trial entry or **as soon as possible after randomisation**.
- **Only the parent(s) who have signed the consent form should have their details inputted onto the contact details form.**
- The email address and mobile number are required to send the parent questionnaires, and the postal address is required to send supplement. A temporary address can be included and updated at a later date if required. Parents can only register their infant on the study app if their contact details have been inputted into the randomisation website.
- If both a mobile number and email address are provided, the recipient will receive both a text message and an email. Ideally both are provided so that parents are contactable if contact details change or are inputted incorrectly.
- If an infant is being discharged to somewhere other than the parental home, please ensure that the DOLFIN Study team has the correct address for supplement deliveries (by updating the infant’s contact details via the randomisation website).

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To add or update contact details after randomisation has been completed:

- Login to the randomisation website and click 'Recruitment List' **Menu**

Latest 3 participants		
Study no	Date randomised	Time since randomisation
10691	20/07/22 16:40	about a day
10686	18/07/22 16:43	3 days
10675	13/07/22 17:07	about a week

Please select one of the following options:

1. Randomise infant
- Randomise infant with random data
2. Recruitment list (31) 
3. Login packs
4. Pack list
5. Pack list (detailed)

- Find the study ID for infant you would like to add contact details for and click 'Edit'

Study no	Recruiting centre	Time randomised	Pack	Print	Edit contact details
12715	Leicester Royal Infirmary	30/10/23 11:53	C2279	<input type="button" value="Print"/>	<input type="button" value="Edit"/> 
12704	Addenbrooke's Hospital, Cambridge	26/10/23 13:51	C6595	<input type="button" value="Print"/>	<input type="button" value="Edit"/>

- Add or update contact details and click 'Save'

Once the infant has been randomised and the Contact Details form completed, please then complete the:

- For all infants: **Trial Entry Form** on OpenClinica
- For infants recruited after discharge home: **Post-discharge Form** on OpenClinica (replaces Transfer/Discharge Form for infants not recruited in hospital)
- For HIE infants: **Neonatal Encephalopathy form** on OpenClinica.

Follow up to ensure completion of the **DOLFIN Baseline Questionnaire**, which should be completed as soon as possible around the time of randomisation. This should ideally be completed by the mother, if she has provided consent by signing the DOLFIN consent form (see **Guidance Sheet 2 – In-person and Remote Informed Consent**). If you have entered the mother's email address and/or mobile number into the contact details section as outlined above, an email/text message will have been sent to her with a link to complete the form. A paper copy may also be provided. See **Guidance Sheet 6 – Data Collection Forms**).

On the contact details form select which option the parents will be using to report adherence: app, OpenClinica or paper diary. This is important so that the relevant processes can be put in place.

Further details can be found in **Guidance Sheet 6- Data Collection Forms**.

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