

Prior to randomisation, please ensure:

- Written informed consent has been obtained
- Final eligibility sign-off has been obtained from a delegated medically trained doctor or ANNP (need not be the Principal Investigator)

Randomising infants

- To randomise the infant, access the online randomisation website at <https://rct.npeu.ox.ac.uk/surfon/login.php>

Log into the randomisation program using your centre log-in details (located in your Site Document Box).

- Select your centre from the drop-down list
- Enter your username
- Enter your password

Once you are logged in, click **“Enter infant”**:



- Complete questions related to eligibility of the infant. The person completing the form must be on the **Delegation Log** for randomisation.
- If you are happy that the data are correct, click **“Continue”**. Any data that suggest the infant is ineligible will be flagged up.

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 A: Eligibility

Time of randomisation: 8 Jun 2020 20:19

A1. What was the expected date of delivery (EDD)? / /

A2. What is the infant's date of birth? / /
 : 24hr clock

A3. What is the infant's sex?

A4. What is the FiO_2 needed to maintain $SaO_2 \geq 92\%$?

A5. Is the work of breathing clinically significant, regardless of FiO_2 ?

Answer must be Yes to continue

A6. Is there a clinical decision to provide non-invasive respiratory support?

A7. Do you have written parental informed consent for the infant's participation?

Who signed the consent form?

A8. Do you have written consent for the mother's participation to complete questionnaires?

A9. Does the infant have a major structural or chromosomal abnormality?

A10. Does the infant have no realistic prospect of survival?

A11. Has the infant had prior intubation and/or surfactant administration?

A12. Does the infant have known or suspected hypoxic ischaemic encephalopathy?

A13. Does the infant have a congenital abnormality of the upper or lower respiratory tract?

A14. Does the infant have a known or suspected neuromuscular disorder?

A15. Was the infant one of a multiple pregnancy?

If **Yes**, has a sibling from this pregnancy already been recruited into this study?

Name of person completing this form:

[Home](#)

- **Check that the data are correct.** If any information is incorrect, click **“Amend”** and enter the corrected information before clicking **“Complete”**

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

Section A: Eligibility

Time of randomisation: 8 Jun 2020 20:19

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

If correct, click 'complete'

Complete **Amend** **Cancel**

A1. What was the expected date of delivery (EDD)? 01 / July / 2020

A2. What is the infant's date of birth? 08 / June / 2020
20 : 00 24hr clock

A3. What is the infant's sex? Male

A4. What is the FiO₂ needed to maintain SaO₂ ≥ 92%? 0.4

A5. Is the work of breathing clinically significant, regardless of FiO₂? Yes

A6. Is there a clinical decision to provide non-invasive respiratory support? Yes

A7. Do you have written parental informed consent for the infant's participation? Yes
Who signed the consent form? Mother

A8. Do you have written consent for the mother's participation to complete questionnaires? Yes

A9. Does the infant have a major structural or chromosomal abnormality? No

A10. Does the infant have no realistic prospect of survival? No

A11. Has the infant had prior intubation and/or surfactant administration? No

A12. Does the infant have known or suspected hypoxic ischaemic encephalopathy? No

A13. Does the infant have a congenital abnormality of the upper or lower respiratory tract? No

A14. Does the infant have a known or suspected neuromuscular disorder? No

A15. Was the infant one of a multiple pregnancy? Yes
If **Yes**, has a sibling from this pregnancy already been recruited into this study? No

Name of person completing this form:

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If incorrect, click 'amend' and correct data

On the randomisation screen, the infant will be allocated to *Early Surfactant Therapy* or *Expectant Management* and given a **SurfON Study number**. Note that multiples will be randomised to the same arm:

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

Section B: Randomisation

SurfON study number:
10026

Allocation
Early surfactant therapy

Date and time of randomisation
08/06/2020 20:19

Please record study number **10026** on the Consent Form and any other trial documentation for this infant.
Please press the **Print** button below to generate a pdf which you should print out.

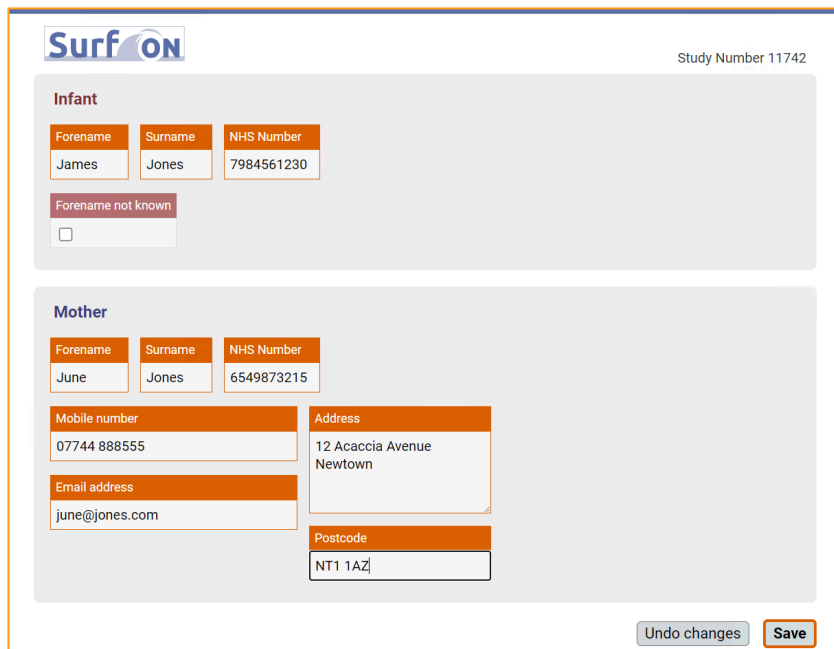
Thank you for entering this infant into the SurfON study.
Please click the link below to log out

[Log out](#)

- Enter the **Study number** immediately onto the **Consent Form** and **Mother's Trial Entry Questionnaire** if applicable
- Click "**Print**" and file a copy in the **Data Collection File**

Contact Details Form

After randomisation, click the “**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), email address, telephone number and postal address. Please note that the mother’s email address is frequently missed on this form so please collect this at randomisation
- Once you have randomised the infant and completed the Contact Details form, complete the **Trial Entry Form** on **OpenClinica** and **Mother’s Trial Entry Questionnaire**. Request completion of the Trial Entry Questionnaire if the mother has consented to do so. ***This should be completed as soon as possible around the time of randomisation.***

Further details can be found in **Guidance Sheet: 5 Case Report Forms**.

Technical difficulties

If you experience technical difficulties with internet access or the Randomisation website, please call the number/s below.

- During normal office hours, contact the SurfON study team on:
01865 289 437 / 738

In the case of urgent out-of-hours queries, please phone 0800 1385 451

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The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.