UKCCRG
UK Critical Care Research Group

Newcastle University

NHS
The Newcastle upon Tyne Hospitals
NHS Foundation Trust

SIGNET

Statins for Improving orGaN outcomE in Transplantation

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SIGNET Cascade training slides v1.0 2021 07 12

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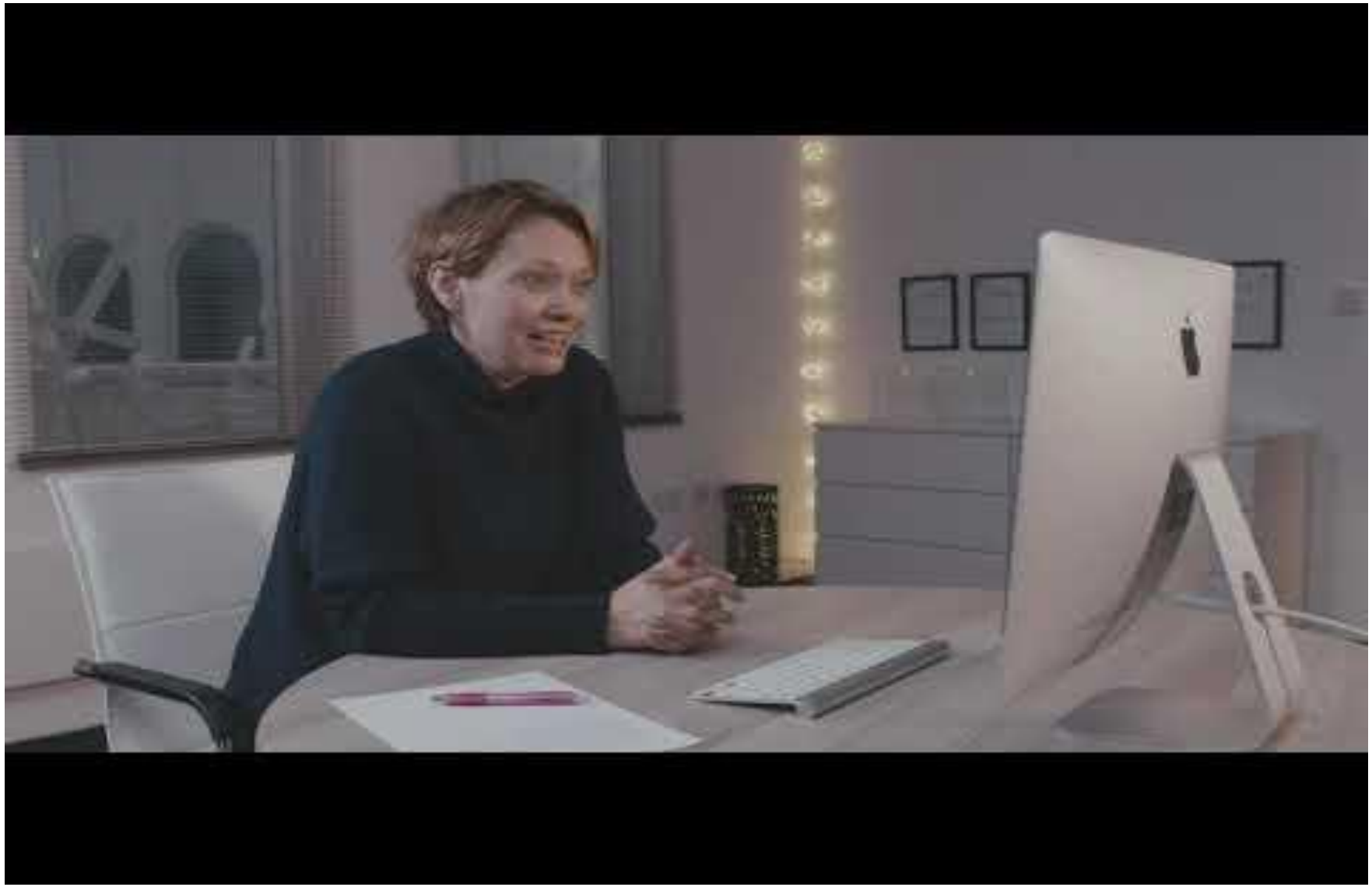


SIGNET

SIGNET is a study in organ donors, investigating whether a single dose of Simvastatin improves outcomes in recipients. Your role is:

ICU Doctor - reconfirm if the patient is eligible and prescribe the Simvastatin. Document this on the source data form handed to you by the SNOD.

Bedside Nurse – Administer the Simvastatin following local policies. Document this on the source data form handed to you by the SNOD.

Inclusion/ Exclusion Criteria

Inclusion Criteria

- Within a recruiting ICU
- Patient confirmed dead by neurological criteria (DBD)
- Consent for organ donation in place
- Study specific consent

Exclusion Criteria

- Aged <18 years
- Planned donation after cessation of circulation (DCD)
- Known allergic hypersensitivity to Simvastatin

The Intervention

- Patients will be randomised to receive either:
  - 80mg Simvastatin tablet in addition to standard care
  - Standard care alone
- Simvastatin from ward stock – no formal drug accountability
  - Prescribed on medication chart as per local hospital policy
    - Eg "Simvastatin 80mg once NG, SIGNET study intervention"

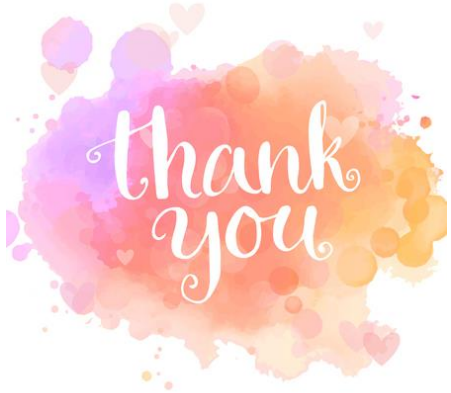
- Bedside nurse administers Simvastatin via NG tube
  - NG tube will need to be administered if not already in place
  - 80mg Simvastatin tablet crushed and mixed 20mls sterile water
  - Follow local policy for administering medication via NG tube
  - Flush NG tube 10ml sterile water following administration

Unblinding

The donor's allocation will be blinded to the theatre, retrieval and recipient care teams; they will not know if the donor received the Simvastatin. This is so that they don’t treat the recipient differently, which may affect the study outcomes. Care should be taken not to accidentally unblind the donor. **Do not document in the medical notes whether Simvastatin was given.**

The recipient treating consultant may contact you to find out whether the donor received Simvastatin or not if the recipient is predicted to come to harm/ if they may need to decline the organ.

If you are asked to unblind the patient's allocation, please ask them to call the PI/ ICU consultant.



Any Questions?

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