EudraCT: 2020-002459-40
The BREAST-AB Trial
Consent form version 2.0

INVESTIGATORS VERSION: Is to be signed and collected with written consent

Informed consent for participation in a health science research project

Titel: Prophylactic treatment with locally applied antibiotics on breast implants for breast reconstruction

Original titel: Prophylactic treatment of breast implants with a solution of gentamicin, vancomycin and cefazolin antibiotics for women undergoing breast reconstructive surgery: a randomized controlled trial (The BREAST-AB trial)

Declaration from the trial participant:

I have received written and oral information about the trial, and I have obtained sufficient knowledge regarding the trial's purpose and methods including any advantages and disadvantages related to participation in the trial.

I am aware that it is voluntary to participate, and that I can withdraw my consent at any time during the trial without losing my current or future rights to treatment.

I hereby give consent to participate in the trial and that those responsible for the trial can obtain information from my medical record. I have received a copy of this consent form along with a copy of the participant information regarding the trial.

Name of the participant: _____

Date: _____ Signature: _____

Do you wish to be informed about the results of the trial?

Yes _____ No _____

Declaration from the investigator providing the oral information:

I hereby declare that the trial participant has received oral and written information regarding the trial.

In my opinion, sufficient information has been provided to enable a decision on participation in trial.

The name of the investigator who provided the information:

Date: _____ Signature: _____

This study is approved by the Danish Data Protection Agency (P-2019-219), The Ethics Committee of the Capital Region (H-20046592) and the Danish Medicines Agency (2020070016)

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PARTICIPANTS VERSION: handed over to the participant

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