# PREHEAT Trial - local heat preconditioning and wound healing

Submission date [X] Prospectively registered Recruitment status 25/02/2015 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 25/02/2015 Completed [X] Results Individual participant data **Last Edited** Condition category 18/06/2019 Cancer

#### Plain English summary of protocol

Not provided at time of registration

## **Contact information**

#### Type(s)

Scientific

#### Contact name

Miss Billie Coomber

#### Contact details

St Thomas's Hospital 249 Westminster Bridge Road London United Kingdom SE1 7EH

### Additional identifiers

Protocol serial number 18442

## Study information

#### Scientific Title

A feasibility study to evaluate local heat preconditioning with respect to its effects on wound healing after reconstructive breast surgery in patients with breast cancer—a single blind randomised controlled trial

#### Acronym

#### **PREHEAT**

#### Study objectives

The aim of this study is to evaluate local heat preconditioning with respect to its effects on wound healing after reconstructive breast surgery in patients with breast cancer.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

NRES Committee South Central - Hampshire B, 05/12/2014, ref: 14/SC/1334

#### Study design

Randomised; Interventional; Design type: Prevention

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Topic: Cancer; Subtopic: Breast Cancer; Disease: Breast

#### **Interventions**

The intervention is heat preconditioning the breast over the nipple-areola complex. The heat will be delivered by hot water bottles at a temperature of 43degC in three thirty minute cycles interrupted by 30-minute breaks where the breast is allowed to cool. The control group will not be required to perform any intervention. The follow up will be via clinical assessment of healing.

#### Intervention Type

Other

#### Primary outcome(s)

Development of skin necrosis of the breast post operatively, measured by clinical assessment (area of necrosis measured in mm2) on post-operative days 1-30

#### Key secondary outcome(s))

Added 12/06/2018:

- 1. Recruitment rate (number randomised/number eligible)
- 2. 30-40 day follow-up rate
- 3. Level of compliance with heating protocol
- 4. Length of hospital stay
- 5. Rates of surgical/conservative management of skin necrosis necrosis was measured at the first outpatient appointment (usually day 12-16) until 30-40 days post surgery

#### Completion date

09/03/2017

## Eligibility

#### Key inclusion criteria

- 1. All females over the age of 18
- 2. Patients undergoing skin sparing mastectomy and immediate breast reconstruction (autologous & implant)
- 3. All diabetics, smokers and postradiotherapy patients will be included
- 4. All BRCA carrier prophylactic mastectomies with immediate breast reconstruction

#### Added 05/12/2016:

5. Patients undergoing nipple-sparing mastectomy

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Female

#### Total final enrolment

141

#### Key exclusion criteria

1. Any delayed (2stage) reconstruction patients

#### Added 05/12/2016:

- 2. Latex allergy
- 3. Inflammatory breast cancer

#### Date of first enrolment

09/03/2015

#### Date of final enrolment

09/03/2017

#### Locations

#### Countries of recruitment

**United Kingdom** 

England

Study participating centre
St Thomas's Hospital
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

## Sponsor information

#### Organisation

Guy's & St Thomas' NHS Foundation Trust & King's College London (Comprehensive)

#### **ROR**

https://ror.org/00j161312

## Funder(s)

#### Funder type

Government

#### **Funder Name**

National Institute for Health Research

#### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

#### **Funding Body Type**

Government organisation

#### Funding Body Subtype

National government

#### Location

United Kingdom

#### **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

## **IPD sharing plan summary** Other

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article	results	11/01/2019	18/06 /2019	Yes	No
<u>Protocol article</u>	study protocol and statistical analysis plan	17/01/2018		Yes	No
Basic results		19/03/2018	12/06 /2018	No	No
HRA research summary			28/06 /2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11 /2025	No	Yes
Study website	Study website	11/11/2025	11/11 /2025	No	Yes