

PREHEAT Trial - local heat preconditioning and wound healing

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Prevention

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
Protocol article	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
Study website	Study website	11/11/2025	11/11/2025	No	Yes