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PREHEAT Trial - local heat preconditioning and wound healing

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://reconstructivesurgerytrials.net/clinical-trials/preheat/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
09/03/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 180; UK Sample Size: 180

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
England

United Kingdom

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)

Sponsor details
Imaging Sciences
The Rayne Institute
Lambeth Wing - 4th floor St Thomas' Hospital
London
England
United Kingdom
SE1 7EH

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
We are intending to publish in 2017 in a scientific journal. We also plan to disseminate our results via the patient support groups for breast reconstruction.

Added 12/06/2018:
The manuscript is currently under peer review.

Intention to publish date

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?
Protocol article	study protocol and statistical analysis plan	17/01/2018		Yes	No

Basic results		19/03/2018	/2018	No	No
Results article	results	11/01/2019	18/06 /2019	Yes	No
HRA research summary			28/06 /2023	No	No