ISRCTN59740680 https://doi.org/10.1186/ISRCTN59740680

Phase II randomised non-blinded trial of removal of vacuum on wound drainage bottles versus leaving vacuum intact

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 20/02/2020	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Uccio Querci della Rovere

Contact details
Breast/Surgical
Royal Marsden NHS Trust
Downs Road
Sutton
United Kingdom
SM2 5PT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0258184667

Study information

Scientific Title
-

Study objectives
To estimate the incidence in patients receiving standard care and also in patients having the vacuum removed early.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised, non-blinded (Phase II)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cancer: Breast

Interventions
Standard care vs vacuum removed early.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To estimate the incidence of seroma in women having standard axillary care (vacuum left intact) and women having vacuum removed on 3rd day.

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/01/2006

Completion date
08/12/2006

Eligibility

Key inclusion criteria
50 RMH patients who are adult women aged over 18 years old and who are undergoing axillary dissection for breast cancer.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
50

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
11/01/2006

Date of final enrolment
08/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Breast/Surgical
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The Royal Marsden NHS Foundation Trust (UK)

Funder Name
NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration