

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/02/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0258184667

Study information

Scientific Title

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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