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Women's recovery from sternotomy (WREST) study

Submission date	Recruitment status	[_] Prospectively registered
05/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/02/2009	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-59756

Study information

Scientific Title
Early clinical use of an undergarment (brassiere) in women over a 12 week post-sternotomy recovery period: a randomised controlled trial

Acronym
WREST

Study objectives
To test the efficacy of early clinical use of an undergarment (brassiere) in women over a 12 week post-sternotomy recovery period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Calgary Health Research Ethics Board gave approval on the 20th February 2003.

Study design
Randomised controlled trial

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
First time sternotomy

Interventions
Supplied brassiere (intervention) versus participants' own undergarments (control).

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure

Pain, discomfort and functional status from post-operative period through 12 weeks of follow-up.

Secondary outcome measures
1. Wound healing and antibiotic use
2. Analgesic and antibiotic use

Overall study start date
01/05/2003

Completion date
31/03/2005

Eligibility

Key inclusion criteria
1. Women, aged 18 years and older
2. Having cardiac surgery through first-time median sternotomy
3. Informed consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
480

Key exclusion criteria
1. Who do not speak and read the English language
2. Present in a clinical preoperative state that suggested a prolonged recovery
3. Do not have telephone access
4. Appear unlikely to complete data collection procedures

Date of first enrolment
01/05/2003

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
Canada

Study participating centre
University of Calgary
Calgary
Canada
T2N 1N4

Sponsor information

Organisation
University of Calgary (Canada)

Sponsor details
2500 University Drive N.W.
Calgary
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T2N 1N4

Sponsor type
University/education

Website
http://www.ucalgary.ca/

ROR
https://ror.org/03yjb2x39

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-59756)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	study design	01/05/2005		Yes	No
Results article	results	01/12/2006		Yes	No