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Does massage during a long operation reduce pain in the recovery period?

Submission date	Recruitment status	[ ] Prospectively registered
16/06/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/07/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/12/2020	Signs and Symptoms	[ ] Record updated in last year

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
RPC178

Study information

Scientific Title
The effect of Intra-operative Passive Movement on Non-Surgical Site Pain after breast reconstructive surgery

Acronym
IPM for NSSP

Study objectives
There is no statistically significant reduction in the pain experienced by patients undergoing breast reconstructive surgery who receive intra-operative passive movement (IPM) therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brighton West Research Ethics Committee, 24/01/2008, ref: 07/H111/93

Study design
Prospective double-blinded randomised controlled trial

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Non-surgical site pain

Interventions
Intra-operative passive movements (IPM):
The treatment protocol was devised by the hospital's senior physiotherapists using techniques described by Maitland. The movements have been standardised (each movement is to be performed twice) and will take five minutes. The treatment will be administered once during a natural break in surgery and again at the end of surgery before the patients are taken through to the recovery ward. IPM will not interfere with the surgeon and will be well away from where the surgeon is working. Sterility of the surgical field will be ensured at all times. Trained anaesthetic assistants who are responsible for patient positioning along with the anaesthetists

and surgeons will carry out the treatment. The anaesthetic assistants will be trained by a named researcher, using a DVD designed specially for this IPM therapy.

Control:
Control treatment is passive movements of both upper limbs and lower limbs, and is carried out in sequence over a period of 5 minutes.

The first treatment is during a natural break (mid-surgery), and the second is after completion of surgery. The total duration of the treatment is 10 minutes, and follow up will be 24 hours.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The mean Visual Analogue Scale (VAS) pain score at 1 hour post-operatively.

Secondary outcome measures
The mean cumulative morphine consumption in 24 hours post-operatively.

Overall study start date
01/05/2008

Completion date
01/11/2009

Eligibility

Key inclusion criteria
Women over the age of 18 years undergoing delayed deep inferior epigastric perforators (DIEP) and trans-rectus abdominis muscle (TRAM) breast reconstructive surgery.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
42

Key exclusion criteria

1. Patients who are unable to give full consent or do not wish to take part in the trial
2. Chronic pain patients requiring medication for their condition
3. Patients with allergies or contra-indications to the analgesics or anaesthetic drugs stated in the protocol

Date of first enrolment
01/05/2008

Date of final enrolment
01/11/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Victoria Hospital
Holtye Road
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Sponsor information

Organisation
Queen Victoria Hospital NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.qvh.nhs.uk/

ROR
https://ror.org/03bs2yy11

Funder(s)

Funder type
Government

Funder Name
Queen Victoria Hospital NHS Foundation Trust (UK)

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