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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

#### Contact name

Dr Chetan Patel

#### Contact details

Queen Victoria Hospital Holtye Road E Grinstead United Kingdom RH19 3DZ +44 (0)1342 414000 chetan.patel@qvh.nhs.uk

## 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 E Grinstead United Kingdom RH19 3DZ

# **Sponsor information**

#### Organisation

Queen Victoria Hospital NHS Foundation Trust (UK)

#### Sponsor details

Holtye Road East Grinstead England United Kingdom RH19 3DZ +44 (0)1342 414573 sarah.dawe@qvh.nhs.uk

#### 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