Can exhalation while rising from bed relieve motion-induced pain after abdominal surgery?

Submission date	Recruitment status	Prospectively registered		
		Protocol Statistical analysis plan		
01/03/2019	Completed	[X] Results		
Last Edited 20/09/2021	Condition category Other	Individual participant data		

Plain English summary of protocol

Background and study aims

Wound pain interferes with the movement of post-operative patients, especially when they try to rise from the bed. Exhalation may release the tension of the abdominal wall and may reduce the motion pain due to rising.

Who can participate? Post-operative patients of open renal biopsy or inguinal hernia repair surgery within 3 days after surgery.

What does the study involve? The intervention involves patients breathing out while rising from bed.

What are the possible benefits and risks of participating? Relieving motion-induced pain of post-operative wound may facilitate the physical activity of patients and may accelerate functional recovery.

Where is the study run from? Sendai Social Insurance Hospital.

When is the study starting and how long is it expected to run for? August 2011 until January 2012.

Who is funding the study? Tohoku University School of Medicine.

Who is the main contact? Hisao Sakagami

Contact information

Type(s) Scientific **Contact name** Mr Hisao Sakagami

Contact details

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers

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Study information

Scientific Title

Rising from the bed with exhalation to relieve motion-induced pain of post-operative wound after abdominal surgery: a non-randomised study

Study objectives

Rising from the bed with exhalation may relieve motion-induced pain of post-operative wound after abdominal surgery

Ethics approval required Old ethics approval format

Ethics approval(s)

Approved 01/11/2011, The Ethical Review Committee of Sendai Social Insurance Hospital (Currently JCHO Hospital) (Tsutumi-machi 3-16-1, Aoba-ku, Sendai, Japan; soumu@sendai.jcho.go.jp), ref: 2011-13.

Study design Interventional non-randomised study

Primary study design Interventional

Secondary study design

Non randomised study

Study setting(s) Hospital

Study type(s) Quality of life

Participant information sheet No participant information sheet available

Health condition(s) or problem(s) studied Pain after open renal biopsy or inguinal hernia repair surgery

Interventions

The intervention involves telling patients to breath out while rising from bed. Self-rated pain (measured using the visual analogue scale) is reported after rising and is compared to the pain while rising without exhalation. There is no follow up.

Intervention Type Behavioural

Primary outcome measure

Subjective pain assessed by visual analog scale immediately after rising up with or without exhalation

Secondary outcome measures There are no secondary outcome measures

Overall study start date 01/08/2011

Completion date

31/01/2012

Eligibility

Key inclusion criteria

Patients who have undergone open renal biopsy or inguinal hernia repair surgery within the past 3 days.

Participant type(s) Patient

Age group Adult

Sex Both **Target number of participants** 77

Total final enrolment 77

Key exclusion criteria1. Post-operative patients without wound pain2. Incapable of rising up from their bed due to motor deficit.

Date of first enrolment 01/11/2011

Date of final enrolment 28/01/2012

Locations

Countries of recruitment Japan

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Study participating centre
Sendai Social Insurance Hospital
Tsutumi-machi 3-16-1, Aoba-ku
Sendai
Japan
981-8501
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Sponsor information

Organisation Tohoku University School of Medicine

Sponsor details Seiryo-cho 2-1, Aobaku Sendai Japan 980-8575 +81-22-717-8586 info@art.med.tohoku.ac.uk

Sponsor type University/education

Funder(s)

Funder type University/education

Funder Name Tohoku University School of Medicine

Results and Publications

Publication and dissemination plan

Planned publication in BMC Nursing.

Intention to publish date 31/10/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results		26/05/2020	20/09/2021	No	No