

# Hypnotherapy and recovery after keyhole surgery for the gall bladder

<b>Submission date</b> 22/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/12/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/03/2020	<b>Condition category</b> Surgery	<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
YOR-A01504

# Study information

## Scientific Title

Pre-operative hypnotherapy and recovery after laparoscopic cholecystectomy: a randomised controlled trial

## Study objectives

Participants randomised to receive a single session of taped self-hypnosis prior to keyhole surgery to remove the gall bladder will have lower pain levels 24 hours after surgery than participants who listen to a tape of white noise prior to their surgery.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

East Yorkshire and North Lincolnshire Research Ethics Committee (part of the UK 's NHS National Research Ethics Service), 31/08/2010, ref: 10/H1304/21

## Study design

Single-centre parallel two-group randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised parallel 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

Surgical removal of the gall bladder for the treatment of cholelithiasis (gallstones) or cholecystitis (inflammation of the gall bladder)

## Interventions

1. Audiotape of hypnotherapy (created and recorded by an experienced clinical hypnotherapist)
2. Audiotape of white noise (white noise produced by combining sounds of all different frequencies together. White noise is frequently used to mask other sounds especially unpleasant or unwanted sounds. Can be used therapeutically.)

Duration of intervention is an hour (listen to hypnotherapy tape or tape of white noise on one occasion prior to surgery - each tape lasts about an hour). Duration of follow up is 4 months.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Pain using a numeric pain scale where 0 is 'no pain' and 10 is 'worst pain imaginable'. Primary outcome is level of pain 24 hours after surgery.

**Secondary outcome measures**

1. Pain using a numeric pain scale where 0 is 'no pain' and 10 is 'worst pain imaginable'. Secondary pain outcomes measured at 4 hours, 4 days, 1 week, 2 weeks after surgery.
2. Use of pain relief medication in first two weeks after surgery
3. Blood pressure and heart rate measured on admission, at anaesthetic induction, 30 minutes into surgery, 30 minutes after regaining consciousness, 6 hours, 12 hours and 24 hours after surgery
4. Quality of life using the SF-36. Measured before surgery, day 1 after surgery, 1 week, 4 weeks and 4 months after surgery

**Overall study start date**

01/12/2010

**Completion date**

01/06/2012

**Eligibility****Key inclusion criteria**

1. Aged 18 - 90 years, either sex
2. Diagnosis of cholelithiasis and/or cholecystitis
3. Requiring elective laparoscopic cholecystectomy
4. Under the care of two named surgeons at York Hospital

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

60

**Key exclusion criteria**

1. Under the age of 18 or over the age of 90 years
2. Diagnosis of cholelithiasis but requiring an open cholecystectomy
3. Requiring surgery for reasons other than cholelithiasis and/or cholecystitis
4. Requiring emergency laparoscopic cholecystectomy
5. Received hypnosis within the past 3 months
6. Current and/or past history of psychiatric illness
7. Regular use of prescribed analgesics (i.e. on repeat prescription for analgesics)
8. Severe cognitive impairment
9. Hearing impairment (the study involves listening to audio tapes)
10. Not able to understand English

**Date of first enrolment**

01/12/2010

**Date of final enrolment**

01/06/2012

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

York Hospital

York

United Kingdom

YO31 8HE

## Sponsor information

**Organisation**

York Teaching Hospital NHS Foundation Trust (UK)

**Sponsor details**

York Hospital

Wigginton Road

York

England

United Kingdom

YO31 8HE

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.york.nhs.uk/>

**ROR**

<https://ror.org/027e4g787>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

York Teaching 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