

Serotonin transporter gene as predictor of recovery after surgery

Submission date 29/04/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/04/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/02/2018	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
6719

Study information

Scientific Title
Serotonin transporter gene polymorphisms as a predictor of recovery after laparoscopic cholecystectomy: a non-randomised interventional screening trial

Study objectives
Recovery from surgery is highly variable. Having a better understanding of factors affecting this is useful in planning surgery, monitoring the effects of surgery and in conducting further

research to improve recovery for future patients. Research has found that psychosocial factors, particularly attitudinal and mood factors, were strongly predictive of surgical outcomes, even after accounting for known clinical factors.

Work is underway to find biological markers for outcomes in major surgery, but there are currently no known biological markers identified for good or poor psychosocial recovery to date. However, the serotonin transporter gene polymorphism represents a possible marker. The promotor region of the serotonin transporter gene is present as homozygous (two short, ss, or two long, ll alleles) or heterozygous. Numerous studies have found that following a major life event, depression was more likely to occur in individuals carrying the short allele (ss, sl).

The aim of the present study is to investigate whether the serotonin transporter gene polymorphism is related to psychosocial recovery after a common operation, laparoscopic cholecystectomy. To do this, we will assess the polymorphic status of 250 individuals due to have laparoscopic cholecystectomy and give them a range of self report questionnaires to fill in before the surgery and 6 weeks after.

Ethics approval required

Old ethics approval format

Ethics approval(s)

York Research Ethics Committee, 29/08/2007, ref: 07/H1311/69

Primary study design

Interventional

Study design

Non-randomised interventional screening trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Topic: Mental Health Research Network; Subtopic: Service Delivery; Disease: Not Applicable

Interventions

1. Buccal swab - taken before the operation and analysed for the serotonin gene length polymorphism only
2. Questionnaires - filled in by participants before the operation and 6 weeks after:
 - 2.1. 36-item short form health survey (SF-36)
 - 2.2. Hospital Anxiety and Depression Scale (HAD)
 - 2.3. Beck Depression Inventory (BDI)
 - 2.4. Chalder Fatigue Scale
 - 2.5. Visual Analogue Pain Scale
 - 2.6. Eysenck Personality Questionnaire (EPQ-R)
 - 2.7. Unvalidated questionnaire on pre- and post-operative milestones (e.g. time back to work etc)

Follow up length: 12 months

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Change in score on the Beck Depression Inventory (BDI), scored on a scale of 0 - 63, measured on day before operation and 6 weeks after.

Key secondary outcome(s)

1. Change in scores on Health Anxiety and Depression (HAD) questionnaire, Chalder's Fatigue Scale, Eysenck Personality Questionnaire - Revised and 36-item short form health survey (SF-36), measured on day before operation and 6 weeks after
2. Visual Analogue Scale (VAS), measured day after operation and 6 weeks after
3. Unvalidated questionnaire to assess current health, measured before operation
4. Unvalidated questionnaire to assess common post-operative milestones, measured 6 weeks after operation

Completion date

31/12/2009

Eligibility**Key inclusion criteria**

1. Patients undergoing elective laparoscopic cholecystectomy
2. Male and female, aged 18 - 65 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Patients undergoing open laparoscopic cholecystectomy

Date of first enrolment

01/01/2008

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

31 Shipton Road

York

United Kingdom

YO30 5RE

Sponsor information

Organisation

York Hospitals NHS Foundation Trust (UK)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

BUPA Foundation (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

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?
Results article	results	06/09/2016		Yes	No