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Serotonin transporter gene as predictor of recovery after surgery

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

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
6719

Study information

Scientific Title

Serotonin transporter gene polymorphisms as a predictor of recovery after laporoscopic 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

Study design
Non-randomised interventional screening trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Screening

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

Interventions
1. Buccal swab - taken before the operation an 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 measure
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.

Secondary outcome measures
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

Overall study start date
01/01/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 250; UK Sample Size: 250

Key exclusion criteria
Patients undergoing open laporoscopic cholecystectomy

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
31 Shipton Road
York
United Kingdom
YO30 5RE

Sponsor information

Organisation
York Hospitals NHS Foundation Trust (UK)

Sponsor details
Learning and Research Centre
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
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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/09/2016		Yes	No