ISRCTN25601281 https://doi.org/10.1186/ISRCTN25601281

Genetic and psychometric role in post-surgical acute pain using ASL/regional cerebral blood (rCBF) flow

Submission date 27/10/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/10/2010	**Overall study status** Completed	
Last Edited 15/05/2017	**Condition category** Oral Health	

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

6829

Study information

Scientific Title
Genetic and psychometric role in post-surgical acute pain using ASL/regional cerebral blood (rCBF) flow

Study objectives
Key research questions include: to assess if functional magnetic resonance imaging (fMRI) changes correlate with patient's expressed dental pain (Visual Analogue Scale [VAS]); and to identify what genes are associated with human pain expression and behaviour in acute post-surgical pain in man.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 07/H0808/115

Study design
Multicentre non-randomised observational diagnosis and screening study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Oral & Dental

Interventions
Surgery is undertaken along with MRI scanning and blood tests and psychometric tests.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Whole brain resting state distribution of Cerebral Blood Flow (rCBF) using continuous labelled ASL with multi-shot fast spin echo (FSE).

Secondary outcome measures
1. Cognitive Coping Strategizing Inventory (CCSI) index
2. Center for Epidemiologic Studies Depression Scale (CES-D) score
3. Computerised Visual Analogue Scale (VAS) measures of perceived intensity of post-surgical pain
4. DNA chip analysis blood
5. DNA chip analysis tissue
6. Eysenck Personality Questionnaire - revised version (EPQ-R) 'E (Extraversion)' and 'N (Neuroticism or Emotionality)' scores
7. Immunohistochemical analysis of known pain receptors
8. Schedule for Clinical Assessment in Neuropsychiatry (SCAN) score
9. The Symptom Checklist-90 - Revised (SCL-90-R) score
10. Students' Test Anxiety Questionnaire (STAQ) pre- and post-trait anxiety and state anxiety score
11. Surgical outcome (difficulty score [1 - 4 scale], depth of impaction, surgery time)

Overall study start date
01/11/2007

Completion date
01/03/2012

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned sample size: 45

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2007

Date of final enrolment

19/11/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London Dental Institute
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

Sponsor details
Department of Research and Development KCH
34 Love Walk
London
England
United Kingdom
SE5 8AD

Sponsor type
Hospital/treatment centre

Website
http://www.kch.nhs.uk/

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Industry

Funder Name
Pfizer Limited (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/02/2011		Yes	No