# A randomised controlled study examining binaural beat audio and preoperative anxiety in patients undergoing general anaesthesia for day case surgery

Submission date 30/09/2004	<b>Recruitment status</b> No longer recruiting	[_] Pr [_] Pr
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	[_] St [X] R
Last Edited 13/05/2009	<b>Condition category</b> Signs and Symptoms	[] In

Prospectively registered

] Protocol

Statistical analysis plan

(] Results

] Individual participant data

#### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

### Type(s)

Scientific

# 

Dr D Laws

#### **Contact details**

Department of Anaesthesia Sunderland Royal Hospital Kayll Road Sunderland United Kingdom SR4 7TP +44 (0)191 5656256 ext 42446

# Additional identifiers

EudraCT/CTIS number

#### IRAS number

ClinicalTrials.gov number

# Secondary identifying numbers N0065125468

### Study information

Scientific Title

#### Study objectives

The study will determine whether binaural beat audio has a superior anxiolytic effect than audio alone in patients about to receive general anaesthesia for day case surgery.

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** Not provided at time of registration

**Study design** Randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Not specified

**Study type(s)** Not Specified

Participant information sheet

Health condition(s) or problem(s) studied Signs and Symptoms: Pre operative anxiety

**Interventions** Patients randomised into 1 of 3 groups.

**Intervention Type** Other

**Phase** Not Specified

**Primary outcome measure** Not provided at time of registration **Secondary outcome measures** Not provided at time of registration

Overall study start date 01/06/2003

Completion date 01/12/2005

# Eligibility

**Key inclusion criteria** 3 groups of 36 patients undergoing general anaesthesia for day case surgery.

Participant type(s) Patient

Age group Not Specified

**Sex** Not Specified

**Target number of participants** 108

**Key exclusion criteria** Not provided at time of registration

Date of first enrolment 01/06/2003

Date of final enrolment 01/12/2005

### Locations

**Countries of recruitment** England

United Kingdom

**Study participating centre Department of Anaesthesia** Sunderland United Kingdom SR4 7TP

### Sponsor information

Organisation Department of Health

**Sponsor details Richmond House** 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type Government

Website http://www.dh.gov.uk/Home/fs/en

# Funder(s)

Funder type Government

Funder Name City Hospitals Sunderland NHS 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

#### Study outputs

Output type **Results** article results 01/09/2005

Peer reviewed?

Yes

Patient-facing?

No

Details Date created

Date added