ISRCTN73378715 https://doi.org/10.1186/ISRCTN73378715

Do individuals with red hair need more anaesthetic than those with dark hair?

Submission date
01/01/2012

Recruitment status
Stopped

Registration date
28/02/2012

Overall study status
Stopped

Last Edited
20/08/2013

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hair colour and skin type are mainly determined by variation of one particular gene, the MC1R gene. Nearly everybody with red hair has two copies of this gene which each code for red hair colour and fair skin type. People with dark hair who tan easily have two different versions of this gene.
There is evidence that individuals with red hair may require more anaesthetic than those with dark hair. If hair colour is associated with anaesthetic requirement, knowledge of this will help anaesthetists to provide the right amount of anaesthesia for different individuals. The results of this study may also be of value in the development of new pain-relieving drugs.

Who can participate?
We are asking volunteers to take part in this research project because they have either naturally red hair or naturally dark hair and are scheduled to receive a general anaesthetic. Volunteers must be generally fit and healthy, between 30-50 years old, male or female, and Caucasian.

What does the study involve?
You will receive a general anaesthetic (be put to sleep), as you would in any case for your operation. However, you will be under anaesthesia for about 30 minutes longer than you otherwise would have been. You will be put to sleep by breathing a sweet smelling anaesthetic gas (sevoflurane) through a clear facemask rather than as an injection through a vein, which is the usual practice. You will be asleep within a few breaths. We will take a blood sample (equivalent to less than one tablespoon) to see which genes you have that determine your hair colour. We will then measure the electrical signals from your brain through sticky electrodes on your forehead, to determine how deeply asleep you are. While you are asleep we will also place a plastic tube in your nose to measure temperature (you may need this for your surgery anyway). After this, we will attach sticky electrodes to the front of your thigh, so that we can assess a movement response using an electrical current signal. You will be unaware of this, as you will be asleep throughout the procedure. After completion, your surgery will proceed as planned. You should expect to receive a telephone call at one week following surgery to check if you have any further questions, and to check your wellbeing.

What are the benefits and risks of taking part?
This study will provide no direct benefits to you on this occasion. However, if you have red hair, the information we gain might help you in the future, or other people requiring general anaesthetics. The risks are the same as if you were just coming for your operation. Your anaesthetist will have discussed the additional risks of anaesthesia with you when you are seen before your operation. Routinely, your anaesthetist would put you to sleep using an injection of anaesthetic through a vein. We will ask you to breathe a sweet smelling gas through a clear facemask. Some people do not like the idea of breathing through a mask, but you would normally receive oxygen through a mask in any case. In practice this is not a problem for most people.

Where is the study run from?
This study is run from the Department of Anaesthetics at Southampton General Hospital (University Hospital Southampton NHS Foundation Trust), which is the lead centre. Recruitment is taking place from within this trust, and including the Southampton NHS Treatment Centre. Two other district general hospitals are also centres for recruitment within the nearby Hampshire Hospitals NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
The first patient was recruited into this pilot study in October 2011, and the pilot is expected to continue recruiting September 2012.

Who is funding the study?
This pilot study is non-corporate, and has been organised by the researchers themselves, with local funding. After the pilot has been completed successfully, we will apply for further funding to recruit greater numbers of participants.

Who is the main contact?
Dr Nicholas Goddard
nicholasgoddard@doctors.net.uk

Contact information

Type(s)
Scientific

Contact name
Dr David Smith

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RHM CRI0248

Study information

Scientific Title
Do individuals with red hair need more anaesthetics than those with dark hair? A pilot study

Study objectives
Individuals with red hair need more anaesthetic compared to those with dark hair to achieve a given depth of anaesthesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford B, 26 April 2011, ref: 11/H0605/13

Study design
Observational experimental design pilot study

Primary study design
Observational

Secondary study design
Case-control 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
Anaesthesia requirement

Interventions
08/07/2013: Please note that this trial has been terminated.
The recruitment was slow, also two recent publications on the same topic have answered the question we were investigating, so there was no point in continuing. The relevant publications

are:
Myles PF, et al. Anaesth Int Care 2012; 40; 683
Doufas AG, et al. Anesth Analg 2013; 116:319

Potential participants should have naturally red scalp hair, and pale or fair skin which tans poorly in response to UVR.

Interventions:
1. Measurement of bispectral index (BIS) after 15 minutes of stable anaesthesia at 1 MAC (End tidal vapour concentration 2.1%), following a gas induction with sevoflurane
2. Presence or absence of a movement response to electrical stimulation of the thigh at the end of this period.
3. Detection of MC1R gene variants as confirmed by blood testing and DNA sequencing.

The control group is of individuals with brown or black scalp hair who tan easily in response to UVR (e.g. after frequent sunbathing during an entire summer).

Total duration of study: 25 minutes. Follow up by telephone call at one week.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
The difference in bispectral index (BIS) score between groups

Secondary outcome measures
Frequency (percentage) movement in response to noxious stimulus while under anaesthesia

Overall study start date
01/10/2011

Completion date
01/09/2012

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Males or females
2. Aged between 30 and 50 years of age
3. Are presenting for elective surgery
4. Able to give informed consent
5. Subjects will be American Society of Anesthesiologists (ASA) physical status grade I or II (healthy or with minor / controlled systemic disease)
6. To avoid bias from background population genetics, all subjects will be Caucasian, and of Northern European dissent by self-identification

7. Potential participants should have naturally red scalp hair, and pale or fair skin which tans poorly in response to ultraviolet radiation (UVR).
8. The control group is of individuals with brown or black scalp hair who tan easily in response to UVR (e.g. after frequent sunbathing during an entire summer)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
14 total (7 in each group)

Key exclusion criteria
1. Patients who are taking any of the following as these drugs may modify the response to anaesthesia and the pain reflex:
1.1. Sedatives
1.2. Strong opioid pre-medication
1.3. Regular opioid analgesics
1.4. Psychotropics
1.5. Anti-convulsants
1.6. Recreational drugs of abuse (amphetamines, cocaine, benzodiazepines, opioids, or alcohol excess)
2. If a general anaesthetic has been administered within the last 6 weeks
3. If the patient has possibly built up tolerance to the anaesthetic
4. Subjects who are pregnant
5. Subjects with a body mass index (BMI) greater than 35 kg/m2
6. Subjects with a known allergy or reaction to anaesthetics
7. Subjects with uncontrolled systemic disease (including chronic pain syndrome and heart burn)
8. Recent involvement in other research unless it can be demonstrated that there will be no possible effect or interaction resulting from the existing trial interventions, and permission can be obtained from the sponsor

Date of first enrolment
01/10/2011

Date of final enrolment
01/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Shackleton Department of Anaesthetics
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust (UK)

Sponsor details
c/ Ms Sharon Atwill
Research and Development
Laboratory and Pathology Block
Southampton Centre for Biomedical Research
Southampton General Hospital
Tremona Road
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England
United Kingdom
SO16 6YD

Sponsor type
Hospital/treatment centre

Website
http://www.uhs.nhs.uk/Research

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Anaesthesia, University Hospital Southampton NHS Trust (UK)

Funder Name

Wessex Anaesthetists Research Fund - Department of Anaesthesia, Royal Hampshire County Hospital (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