ISRCTN11684890 https://doi.org/10.1186/ISRCTN11684890

Effects of intravenous lidocaine on somatosensory and motor evoked potentials during spine surgery

Submission date
05/01/2017

Recruitment status
No longer recruiting

Registration date
13/01/2017

Overall study status
Completed

Last Edited
13/01/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Spinal fusion surgery is a type of surgical procedure which joins two or more vertebrae (small bones that make up the spine) together. Multilevel spinal fusion surgery is where this takes place in multiple areas of the spine, and is used for treating serious spinal problems such as spinal deformity such as scoliosis (abnormal twisting of the spine). Somatosensory evoked potentials (SSEPs) and motor evoked potentials (MEPs) are electrical signals in the body, which are commonly monitored during surgical procedures that place the spinal cord at risk. Many general anesthetic agents (drugs used to sedate people for surgery) can affect SSEPs and MEPs in ways that can make them difficult to monitor however. Propofol (an anesthetic) has been shown to better preserve SSEPs and MEPs than many other anesthetic agents, and for this reason, it is commonly used for cases requiring MEP and SSEP monitoring, either on its own or with a low dose of an inhaled agent. Intravenous (through a vein) lidocaine (a numbing agent) has recently been shown to reduce the required propofol dose during surgery, possibly due to pain blocking properties. This is beneficial as it can decrease a patient's risk of complications associated with high doses of propofol. In this study, patients each receive two anesthetic treatment administered in randomized order, one including a higher dose propofol, and the other including lidocaine plus lower dose of propofol. The aim of this study is to find out whether lidocaine can be added to anesthetic management to allow reduction in propofol requirements without affecting SSEPs or MEPs.

Who can participate?
Adults undergoing multilevel spinal fusion surgery.

What does the study involve?
Each study patient alternately receives two anesthetic treatments in a random order. One treatment involves a high dose of propofol and the other treatment involves a lower dose of propofol with lidocaine. In both treatments, the anesthesia is maintained using a range of drugs usually used in anesthesia. Each treatment lasts for a total of two hours. While the treatment is

being given and then at regular intervals throughout surgery, participants have their SSEP and MEP measured using a special monitoring system that measures electrical conductivity in the body.

What are the possible benefits and risks of participating?
There are no direct benefits or risks for patients taking part in the study.

Where is the study run from?
Hospital for Special Surgery (USA)

When is the study starting and how long is it expected to run for?
August 2011 to December 2015

Who is funding the study?
Hospital for Special Surgery (USA)

Who is the main contact?
Dr Ronald Emerson
emersonr@hss.edu

Contact information

Type(s)
Scientific

Contact name
Dr Ronald Emerson

ORCID ID
http://orcid.org/0000-0002-8592-7539

Contact details
Hospital for Special Surgery
535 East 70th Street
New York
United States of America
10021
+1 212 774 2742
emersonr@hss.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12005

Study information

Scientific Title
In patients undergoing multilevel posterior spinal fusion, does the addition of intravenous lidocaine as a component of balanced anesthesia, compared to balanced anesthesia without lidocaine, alter somatosensory and motor evoked potentials?

Study objectives
There will be no differences between tibial nerve cortical somatosensory evoked potential (SSEP) amplitudes and motor evoked potential (MEP) threshold voltages under balanced anesthetic conditions including propofol 50 mcg/kg/hr and lidocaine 1 mg/kg/hr plus propofol 25 mcg/kg/hr.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, Hospital for Special Surgery., 28/03/2012, ref: 12005

Study design
Single-centre randomised cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Multilevel posterior spinal fusion

Interventions
Each study patient alternately receives two anesthetic treatments. The order of administration is determined randomly. The treatments are propofol at 50 mcg/kg/h, or propofol 25 mcg/kg /min + lidocaine 1 mg/kg/h. During both treatments, maintenance anesthesia also includes fentanyl 1mcg/kg/h, ketamine 2 mcg/kg/min and diazepam 10mg. Patients additionally receive isoflurane, typically 0.5%, adjusted as needed by the attending anesthesiologist to maintain steady hemodynamics.

The total duration of each treatment is 120 minutes, and each treatment is administered for 30 minutes prior to logging IONM data for this study. Prior to the institution of the lidocaine

infusion, each patient receives a loading dose at 1mg/kg over 10 minutes. Primary outcome measurements (SSEP amplitude and MEP threshold voltages) are made by a neurophysiological technologist who is blind to the treatment being administered.

Intervention Type
Drug

Drug/device/biological/vaccine name(s)
Lidocaine

Primary outcome measure
1. Somatosensory evoked potential amplitude is measured using a Cadwell Elite intraoperative monitoring system, at 3-5 minute intervals
2. Motor evoked potentials threshold voltage is measured using a Cadwell Elite intraoperative monitoring system, at 10-20 minute intervals

Secondary outcome measures
1. Isoflurane concentration is measured using a General Electric Datex Ohmeda operating room patient monitor at 5 minute intervals
2. Heart rate is measured using a General Electric Datex Ohmeda operating room patient monitor at 5 minute intervals
3. Blood pressure is measured using a General Electric Datex Ohmeda operating room patient monitor at 5 minute intervals
4. Temperature is measured using a General Electric Datex Ohmeda operating room patient monitor at 5 minute intervals
5. Estimated blood loss is measured at the conclusion of the procedure based on cell salvage system data, irrigation and intraoperative blood administration

Overall study start date
15/08/2011

Completion date
16/12/2015

Eligibility

Key inclusion criteria
1. Patients undergoing multi-level posterior spine fusions requiring both somatosensory and motor evoked potential monitoring
2. Ages within the age range of 18 – 70 years.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Allergy to any of the anesthetic medications included in the protocol
2. Current use of medication for Parkinson’s disease
3. Current psychotropic medication
4. History of cardiac arrhythmias
5. Non-English speaking

Date of first enrolment
28/03/2012

Date of final enrolment
05/03/2014

Locations

Countries of recruitment
United States of America

Study participating centre
Hospital for Special Surgery
535 East 70th Street
New York
United States of America
10021

Sponsor information

Organisation
Hospital for Special Surgery

Sponsor details
535 East 70 Street
New York
United States of America
10021
+1 212 774 2742
emersonr@hss.edu

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/03zjqec80

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital for Special Surgery

Results and Publications

Publication and dissemination plan
Planned publication of study results in a peer reviewed journal.

Intention to publish date
02/01/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ronald Emerson (emersonr@hss.edu)

IPD sharing plan summary
Available on request