

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

Submission date 05/01/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/01/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/01/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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