ISRCTN11124844 https://doi.org/10.1186/ISRCTN11124844

Gel vs saline as medium for ultrasound-guided regional anesthesia

Submission date
12/04/2021

Recruitment status
No longer recruiting

Registration date
27/04/2021

Overall study status
Completed

Last Edited
27/04/2021

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The ultrasound-guided technique is the gold standard for procedural guidance in regional anesthesia. Traditionally, ultrasound gel has been used as the medium for ultrasound wave conduction, but the use of aqueous solutions such as D5W or normal saline has been described and kits containing gel or normal saline conducting mediums are commercially available. Ultrasound gel presents potential problems including a theoretical risk for nerve toxicity and cell damage, increased cost, allergic reaction, and difficultly in maintaining a static ultrasound probe position while performing a block; all of these factors are addressed when using normal saline. Previous studies evaluating the image quality for ultrasound-guided central line placement have shown that gel image quality is superior to normal saline, but both provided adequate views for placement of central lines. Regional anesthesia blocks often require more fine resolution to identify nerve structures, but no study to date has evaluated how normal saline compares to gel for ultrasound-guided regional anesthesia.

Who can participate?
Anesthesiology trainees and attending physicians within the Department of Anesthesiology, Perioperative & Pain Medicine at Mount Sinai

What does the study involve?
Anesthesiology trainees and attending physicians are asked to obtain a supraclavicular view (above the collarbone) with one medium before a washout period and then repeat the exercise with the other medium. The view with each medium is saved and two blinded experts grade each view as “proceed with the nerve block” or “not proceed with the nerve block”. If there is a disagreement between the two experts a third expert provides a tie-break.

What are the possible benefits and risks of participating?
Benefits include practising ultrasound skills and using different types of medium. The risk to participants is minimal. They risk others knowing they are participating in a research study. They may have stress associated with being observed while scanning with ultrasound. There is a risk of loss of study information including name, highest level of education, experience level with regional anesthesia, and time to obtaining scans/grade of ultrasound view.

Where is the study run from?
Mount Sinai Hospital (USA)

When is the study starting and how long is it expected to run for?
August 2020 to May 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Garrett Burnett
garrett.burnett@mountsinai.org

Contact information

Type(s)
Scientific

Contact name
Dr Garrett Burnett

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HS#: 20-01288M

Study information

Scientific Title
Ultrasound gel vs sterile saline as conducting medium for ultrasound-guided regional anesthesia

Study objectives
Gel would provide superior images for ultrasound-guided regional anesthesia compared to normal saline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/21/2020, Institutional Review Board of the Mount Sinai School of Medicine (One Gustave L. Levy Place Box 1621 New York, NY 10029, USA; +1 (0)212 824 8200; irb@mssm.edu), ref: HS#: 20-01288M

Study design
Single-centre randomized simulation study with crossover component

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Regional anesthesiology

Interventions
Anesthesiology trainees and attending physicians are asked to obtain a supraclavicular view with one medium before a washout period and then repeat the exercise with the other medium. The view with each medium is saved and two blinded experts graded each view as: “proceed with the nerve block” or “not proceed with the nerve block”. If there is a disagreement between the two experts a third expert provided a tie-break.

Intervention Type
Procedure/Surgery

Primary outcome measure
Acceptable ultrasound image as deemed by the percentage of images that blinded expert reviewer answered “yes” to the question “Would you proceed with the block with this image?”. This will be measured just after image acquisition.

Secondary outcome measures
Quality of ultrasound image measured by a visual analogue scale of 0-10 by a blinded expert reviewer just after image acquisition

Overall study start date
19/08/2020

Completion date
29/05/2021

Eligibility

Key inclusion criteria
Anesthesiology trainee or attending at the Mount Sinai Hospital who completed all required peripheral nerve blocks required by the Accreditation Council for Graduate Medical Education

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
Subject refused after being explained study

Date of first enrolment
05/03/2021

Date of final enrolment
28/05/2021

Locations

Countries of recruitment
United States of America

Study participating centre
Mount Sinai Hospital
1468 Madison Avenue
New York
United States of America
10029

Sponsor information

Organisation
Mount Sinai Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.mountsinai.on.ca/

ROR
https://ror.org/05deks119

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

1. The study protocol has not been published online but is available on request
2. Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Garrett Burnett (garrett.burnett@mountsinai.org). The study data will be kept for 6 months following the publication of the study. Data will include training level, prior use of saline as an ultrasound medium, comfort with supraclavicular blocks, time to obtain supraclavicular block, acceptability of ultrasound image, and quality of ultrasound image. Unidentified data will be shared with researchers inquiring for further analyses, collaboration or additional information if deemed acceptable by the Mount Sinai Institutional Review Board.

IPD sharing plan summary
Available on request