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Safety and performance of a novel device for the administration of regional anaesthesia

Submission date
22/12/2021

Recruitment status
No longer recruiting

Registration date
27/01/2022

Overall study status
Completed

Last Edited
27/01/2022

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Regional anaesthesia procedures require two operators - an anaesthetist who holds an ultrasound scanner and uses this to guide the needle tip placement and a second operator to inject the anaesthetic solution at a required pressure.
It has been reported that anaesthetic solutions are often injected at high pressure.
High pressure can cause damage to nerve fascicles, with serious nerve damage occurring in up to 1% of procedures and transient nerve damage in up to 8% of cases.
SAFIRA® - SAFer Injection for Regional Anaesthesia - allows a single operator, an anaesthetist or anesthesiologist, to conduct the whole regional block at safer pressures.

The study will examine the following questions:
• Does the SAFIRA device perform as intended in routine clinical practice?
• Is the SAFIRA device safe to use as per intended use?
• What is the user feedback regarding acceptability of and confidence in SAFIRA?

Who can participate?
Peripheral nerve block (PNB) procedures involving patients aged > 18 years referred for any type of elective surgery suitable for PNB and who are offered and agree to surgery that will be performed via any ultrasound guidance and/ or nerve stimulation single-injection PNB regional anaesthesia. Any type of PNB will be included in the study.

What does the study involve?
This study will involve 43 regional anaesthesia procedures undertaken by six anaesthetists already trained in the use of the SAFIRA system in one UK hospital site, in order to ascertain the safety and performance of SAFIRA in a ‘real-world’ clinical setting. The study will be entirely observational. The investigation will not involve any clinical investigation or treatment additional to standard care and will not include any patient-orientated research instruments. All patients will undergo treatment according to normal clinical practice.

What are the possible benefits and risks of participating?
Unintentional needle-to-nerve contact, intraneural penetration or intrafascicular penetration during PNB may cause nerve injury which, even if minor and transient, presents a sizeable

problem when the number of PNB procedures are scaled-up to a healthcare system or population level. Patients experiencing more severe and/or persistent nerve injury may experience significant negative consequences in terms of decreased health status, physical function, ability to work and quality of life. Meta-analyses have identified that Anaesthetists cannot rely on ultra sound guidance, nerve stimulation, ‘syringe-feel’ or injection pressure monitoring as indicators of unintentional needle-to-nerve contact, intraneural penetration or intrafascicular penetration. It is possible that the safest way of preventing nerve damage might be to automatically limit local anaesthetic (LA) opening and injection pressure to levels that are not associated with nerve damage. The SAFIRA system is a medical device that limits LA opening and injection pressures to a level of >20psi. This study will assess the safety and performance of SAFIRA in a ‘real-world’ clinical setting. It is important to note that the SAFIRA system has all necessary approvals and is currently in use within the NHS.

Where is the study run from?
Queen Elizabeth Hospital NHS Foundation Trust King's Lynn (UK)

When is the study starting and how long is it expected to run for?
March 2021 to March 2022

Who is funding the study?
Medovate Ltd (UK)

Who is the main contact?
Dr Benjamin Fox, benjamin.fox@qehkl.nhs.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Benjamin Fox

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
293036

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
IRAS 293036

Study information

Scientific Title
Prospective, open, non-controlled, single-arm post-market clinical follow-up investigation to confirm the safety and performance of the SAFIRA system in ultrasound guidance and/or nerve stimulation peripheral nerve block (PNB)

Study objectives
The study will examine:
• Does the SAFIRA device perform as intended in routine clinical practice?
• Is the SAFIRA device safe to use as per intended use, are the known risks acceptable and do any new risks identified impact the benefit-risk ratio?
• What, if any, is the impact on the clinical workflow of PNB procedures when using SAFIRA compared with standard practice?
• What is the user feedback regarding acceptability of and confidence in SAFIRA for performing PNB procedures?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/03/2021, HRA and Health and Care Research Wales (HCRW) (HRA, NHSBT Newcastle Blood Donor Centre, Holland Dr, Newcastle upon Tyne NE2 4NQ, UK; +44 207 972545; HCRW.approvals@wales.nhs.uk), ref: 21/ES/0029

Study design
Prospective open non-controlled single-arm post-market clinical follow-up investigation

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Safety and performance of the SAFIRA system in ultrasound guidance and/or nerve stimulation peripheral nerve block

Interventions
This prospective, open, non-controlled, single-arm post-market clinical follow-up investigation will involve 43 PNB procedures undertaken by up to 6 anaesthetists trained in the use of the SAFIRA system in one UK hospital site; in order to ascertain the safety and performance of SAFIRA in a ‘real-world’ clinical setting. For the purposes of the study any operation that requires more than one simultaneous PNB (e.g. for complex lower limb surgery) will be considered a single PNB procedure. The study will be entirely observational. The investigation will not involve

allocation (or withholding) of any aspect of clinical care, will not involve any clinical investigation or treatment additional to standard care and will not include any patient-orientated research instruments (e.g. multidimensional pain questionnaires) unless routinely used at participating sites. All patients will undergo treatment according to normal clinical practice i.e. as determined by local institutional protocol and/or individual clinician discretion. The principal units of analysis will be PNB procedures undertaken with the SAFIRA system and various procedure-related, patient-related and operator-related variables will be assessed.
In summary, at the participating site a study assessor (SA) - a trained member of the care team not directly involved in the care of patients within the study - will record the following data:
i) Procedural data related to anaesthetists use of the SAFIRA system in patients undergoing any type of elective surgery via any type of PNB involving ultrasound guidance or nerve stimulation;
ii) Routine clinical data (or clinical data potentially available for collection without impacting on patient care) in patients undergoing SAFIRA PNB procedures
iii) Anaesthetists appraisal of the SAFIRA system.
The study will not consider outcome measures of any of the surgeries undertaken using PNB nor will it consider the underlying effectiveness of ultrasound guidance or nerve stimulation.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
SAFIRA system

Primary outcome(s)
1. Time to perform block at ‘Day 0’. This will be defined as time from the first application of the probe on skin for ultrasound guidance or first application of needle on the skin for nerve stimulation to final removal of the PNB local anaesthetic needle.
2. Composite measure of block success at 'Day 0'. This will be defined as adequate block (sufficient blocking of the transmission of nerve impulses as assessed by routine institutional sensory and/or motor testing protocol to allow surgery to proceed) AND no block conversion (avoidance of rescue block) NB: both composite and separate measures of block success will be reported.
3. Safety at ‘Day 0’ measured using a composite measure of evidence of potential acute nerve injury. This will be defined as any patient-reported severe and painful symptoms such as tingling, prickling, burning, uncomfortable pins and needles or any type of electric shock sensation during the PNB procedure AND suspected or confirmed needle-nerve contact, intraneural needle penetration or intrafascicular needle penetration as reported by the anaesthetist NB: both composite and separate measures of potential nerve injury will be reported.
4. Safety at ‘Day 30’ measured using evidence of persistent nerve injury. This will be defined as any documented evidence in the patient medical records of sensory and/or motor deficit including: i) patient-reported chronic, severe and painful symptoms such as tingling, prickling, burning, uncomfortable pins and needles or any type of electric shock sensation; ii) patient-reported limb or muscle weakness or iii) clinician-observed sensory and/or motor deficit lasting longer than 48 hours after surgery. Sensory and/or motor deficit in a different regional area to that of the PNB will be recorded but will be considered separately to sensory and/or motor deficit in the regional area of the PNB.

Key secondary outcome(s))

Measured at 'Day 0' using patient records and questionnaire completed by anaesthetists:
1. Number of needle punctures (any new needle insertion through skin)
2. Number of needle redirects (any needle insertion-withdrawal-insertion of ≥10mm)
3. Block onset time (interval between completion of LA injection and adequate sensory block to permit surgery in distribution of blocked nerve)
4. Event-free SAFIRA assembly/deployment (any suspected or reported issue in any of the steps of the SAFIRA Instruction for Use)
5. SAFIRA malfunction/failure (any event requiring conversion to manual injection)
6. Major complications (cardiac arrest, pneumothorax, death, other (specify))
7. Minor complications (vascular puncture, haematoma, local anaesthetic toxicity, cardiac arrhythmia, systemic hypotension, other (specify))
8. LA volume required
9. Anaesthetists appraisal of the SAFIRA system after completing all each PNB procedure
10. Injection Pressure (How important is limiting LA opening/injection pressure in your own clinical practice: Not at all important/Quite unimportant/Neither unimportant or important /Quite important/Very important)
11. Ease of Use (Compared to usual practice SAFIRA is easy to use: Strongly disagree/Disagree /Neither disagree or agree/Agree/Strongly agree)
12. Effectiveness (Compared to usual practice SAFIRA is effective: Strongly disagree/Disagree /Neither disagree or agree/Agree/Strongly agree)
13. Drawbacks (Compared to usual practice SAFIRA has few drawbacks: Strongly disagree /Disagree/Neither disagree or agree/Agree/Strongly agree)
14. Workload (Compared to usual practice SAFIRA increases workload: Strongly disagree /Disagree/Neither disagree or agree/Agree/Strongly agree)
15. Preference (Compared to usual practice I prefer SAFIRA: Strongly disagree/Disagree/Neither disagree or agree/Agree/Strongly agree)

Measured at 'Day 30' using patient records and questionnaire completed by anaesthetists::
16. Infection at PNB site
17. Falls (any documented inpatient or at home falls in 30 days following surgery)
18. PNB limb trauma (any documented inpatient or at home trauma (scalds, burns, severe pressure sore) in 30 days following surgery)
19. Postoperative 1hr pain score (assessed using standard institutional method)
20. Postoperative 24hr analgesic consumption
21. Length of hospital stay
22. Anaesthetists appraisal of the SAFIRA system after completing all PNB procedures
23. Injection Pressure (How important is limiting LA opening/injection pressure in your own clinical practice: Not at all important/Quite unimportant/Neither unimportant or important /Quite important/Very important)
24. Ease of Use (Compared to usual practice SAFIRA is easy to use: Strongly disagree/Disagree /Neither disagree or agree/Agree/Strongly agree)
25. Effectiveness (Compared to usual practice SAFIRA is effective: Strongly disagree/Disagree /Neither disagree or agree/Agree/Strongly agree)
26. Drawbacks (Compared to usual practice SAFIRA has few drawbacks: Strongly disagree /Disagree/Neither disagree or agree/Agree/Strongly agree)
27. Workload (Compared to usual practice SAFIRA increases workload: Strongly disagree /Disagree/Neither disagree or agree/Agree/Strongly agree)
28. Preference (Compared to usual practice I prefer SAFIRA: Strongly disagree/Disagree/Neither disagree or agree/Agree/Strongly agree)

Completion date

22/03/2022

Eligibility

Key inclusion criteria
PNB procedures involving patients aged >18 years referred for any type of elective surgery suitable for PNB and who are offered and agree to surgery that will be performed via any ultrasound guidance and/ or nerve stimulation single-injection PNB regional anaesthesia. Any type of PNB will be included in the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. PNB procedures involving patients aged < 18 years
2. PNB procedures involving (pre-scheduled) continuous PNB

Date of first enrolment
22/11/2021

Date of final enrolment
01/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital King's Lynn Foundation Trust
Gayton Road
King's Lynn
United Kingdom
PE30 4ET

Sponsor information

Organisation
Queen Elizabeth Hospital King's Lynn NHS Foundation Trust

ROR
https://ror.org/01m6k8878

Funder(s)

Funder type
Industry

Funder Name
Medovate Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 2.0		04/01/2022	No	No