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Performance of a new needle system for lumbar punctures in children with blood cancer (leukemia)

Submission date
28/06/2022

Recruitment status
Stopped

Registration date
08/07/2022

Overall study status
Stopped

Last Edited
18/04/2024

Condition category
Other

[X] 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
Acute lymphoblastic leukemia is the most common type of blood cancer diagnosed in children. At present, the mean long-term survival from this disease is well over 90%. However, the patient's prognosis weakens if the lumbar puncture causes blood leakage into the spinal canal and blast cells enter the cerebrospinal fluid. There is considerable blood leakage in one out of five lumbar punctures in pediatric patients with leukemia on average. In other words, the procedure is considered traumatic.

A new bioimpedance needle system was recently found feasible in lumbar punctures of pediatric patients with leukemia. The device measures electrical resistance at the needle tip and detects when the needle tip reaches the spinal canal. With this device, lumbar punctures were successful at the first attempt in 80% of performed procedures and only one out of ten lumbar punctures was traumatic. The present study compares the performance of the new device with the conventional spinal needle in clinical practice.

Who can participate?
All children with leukemia, whose diagnosis or therapy requires lumbar punctures and who are willing to participate in the study

What does the study involve?
The method used in the patient's first study lumbar puncture is randomly allocated. Thereafter, either a bioimpedance needle system or a conventional spinal needle are alternately used. The maximum number of study procedures per patient is limited to four.

What are the possible benefits and risk of participating?
In the long term, a lower incidence of traumatic lumbar puncture may translate into patients' improved prognosis and event-free survival. The study is conducted within the usual clinical workflow of pediatric hemato-oncology clinics. Thus, taking part in the study does not require any extra effort from the participant and there are no additional risks of harm or injury.

Where is the study run from?
Tampere University Hospital (Finland)

When is the study starting and how long is it expected to run for?
January 2022 to August 2024

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
1. Dr Sauli Palmu (Finland)
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2. Dr Harri Sievänen (Finland)
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
IQ-LP-04

Study information

Scientific Title
Success and complications in lumbar punctures of pediatric patients with leukemia: A randomized clinical crossover trial of a bioimpedance needle system versus conventional procedure

Study objectives
The performance of the bioimpedance needle system (IQ-Tip system) is at least comparable to the conventional spinal needle regarding the incidence of traumatic lumbar punctures in pediatric hemato-oncology patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/05/2022, Regional Ethics Committee of the Expert Responsibility Area of Tampere University Hospital (TAYS Research Services, PO Box 2000, 33521, Tampere, Finland; +358 50 3295 667; eettinen@pshp.fi), ref: R22039L

Study design
Multicenter randomized crossover noninferiority trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diagnostics and intrathecal treatment of pediatric patients with leukemia

Interventions
Patients' lumbar puncture procedures are alternately performed either with the IQ-Tip system (study arm A) or the conventional spinal needle (study arm B). The maximum number of procedures per patient is four and the method of the first procedure is randomly assigned yielding two possible sequences (either ABAB or BABA)

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
Incidence of traumatic lumbar puncture measured as the proportion of traumatic lumbar punctures (threshold >/= 10 erythrocytes/µl in a cerebrospinal fluid sample) out of all lumbar puncture procedures performed in the given arm after the data collection of the study is completed

Key secondary outcome(s))
1. First puncture success rate measured as the proportion of successful lumbar puncture procedures at the first attempt (one skin penetration) out of all lumbar puncture procedures performed in the given arm after the data collection of the study is completed
2. Incidence of post-dural puncture headache (PDPH) measured as the proportion of lumbar puncture procedures with subsequent PDPH out of all lumbar puncture procedures performed in the given arm after the data collection of the study is completed

Completion date
31/08/2024

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Aged between 1 and 18 years old at the beginning of the study
2. Diagnosis or treatment plan requires multiple lumbar puncture procedures for collecting cerebrospinal fluid samples and injecting intrathecal therapy
3. Planned lumbar puncture procedures will be performed with 22G Quincke-type spinal needles
4. At least two lumbar puncture procedures left in the patient’s treatment protocol
5. Both the parent(s) and the patient, depending on the patient’s age, give a signed informed consent before the first study lumbar puncture procedure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit

1 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. Parent(s) and/or the patient refuse to participate in the trial
2. Parent(s) and/or the patient are considered unable to give informed consent
3. Temporary contraindication to performing a lumbar puncture procedure

Date of first enrolment
11/05/2023

Date of final enrolment
31/07/2024

Locations

Countries of recruitment
Finland

Study participating centre
Tampere University and Tampere University Hospital
Tampere Center for Child, Adolescent and Maternal Health Research
Faculty of Medicine and Health Technology
Teiskontie 35
Tampere
Finland
33520

Study participating centre
New Children’s Hospital
Helsinki University Hospital
Department of Pediatric Hematology
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Stenbäckinkatu 9
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Study participating centre

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Study participating centre
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Sponsor information

Organisation
Injeq Plc

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to reasons pertaining to ethics and data protection of health data of a relatively rare disease

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/07/2023	21/07/2023	Yes	No