Comparison of the non-invasive intracranial pressure Headsense monitor vs lumbar cerebrospinal fluid pressure measurements

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Primary Objective To measure the agreement between ICP (through Headsense monitor) and lumbar CSF pressure (through a lumbar puncture).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Increased intracranial pressure and hydrocephalus
Study type	Observational non invasive

Summary

ID

NL-OMON42476

Source
ToetsingOnline

Brief title
Comparison of the non-invasive intracranial pressure vs LP

Condition

- Increased intracranial pressure and hydrocephalus

Synonym
brain pressure, Intracranial pressure

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: De firma Headsense Medical Ltd;voorziet de

onderzoeksgroep kosteloos de Headsense apparatuur en geeft de tablet monitor in bruikleen gedurende het onderzoek.

Intervention

Keyword: Headsense monitor, Lumbar CSF pressure measurement, Non-invasive ICP measurement

Outcome measures

Primary outcome

Accuracy analysis: The main goal of the study is to validate the accuracy of

HeadSense*s non-invasive ICP monitor. In order to validate the accuracy of the

HeadSense*s device, a statistical comparison will be done between the ICP

values from both the HeadSense*s device and CSF pressure (during LP) using

Pearson*s correlation analysis of the paired measurements

Secondary outcome

None

Study description

Background summary

Intracranial pressure (ICP) and intracranial hypertension
ICP is the pressure inside the skull and thus in the brain tissue and cerebrospinal fluid (CSF). ICP is measured in millimeters of mercury (mmHg) or cm H2O and, at rest, is normally 7-15 mmHg for a supine adult, and becomes negative (averaging *10 mmHg) in the vertical position. An increase in pressure can cause headache, however most headaches are not the result of an increased intracranial pressure. In case of a suspected intracranial hypertension patients undergo a lumbar puncture with CSF pressure as a marker of ICP. A lumbar puncture is an invasive and sometimes painful procedure, which causes post-dural puncture headache in up to 20% of patients. Thus, there is a demand for a non-invasive and accessible technique that can assess ICP in patients.

New non-invasive ICP Monitor from Headsense
The HeadSense device is based on advanced signal analysis algorithms that

analyze an acoustic signal that is generated by the device. The acoustic signal is transmitted using a small transmitter, placed in the patient*s ear, and picked up by an acoustic sensor placed in the other ear. The signal is then analyzed using proprietary algorithms, and the ICP value is displayed to the user in mmHg which is the medical standard units for ICP measurement. (see appendix for comparison of invasive and non-invasive ICP measurements).

Study objective

Primary Objective
To measure the agreement between ICP (through Headsense monitor) and lumbar CSF pressure (through a lumbar puncture).

Study design

In this study we will prospectively collect relevant clinical data on 20 neurological patients who are being referred for an elective lumbar puncture (eg. suspected multiple sclerosis, raised intracranial hypertension etc). Each enrolled patient will be monitored in parallel to the lumbar puncture with the HeadSense*s ICP monitor. Subjects who meet the study*s inclusion and exclusion criteria will be enrolled in the study.

Step 1: 10 minute measurement of Headsense monitor. Once the patient is inclined with his upper body 30 degrees to the bed the pressure values, the clinical procedure can begin. The device must be preset in a continuous monitoring mode. The continuous monitoring allows a loop of measurements for an unlimited time in a rate of four measurements per minute.

Step 2: 10 minute measurement of Headsense monitor in supine position.

Step 3: Patient will be placed in a left lateral position. The lumbar puncture will be done using a 22 gauge atraumatic lumbar puncture needle (e.g., Pajunk Sprotte needle) The CSF pressure will be measured using a standard column manometer.

Step 4: 10 minute measurement of Headsense monitor in supine position.

Lumbar puncture and headsense measurement will be done by two different doctors and they will not share measurement values during the procedure.
After the study the patient*s ears will be examined for internal ear infection or irritation that might be caused by the ear buds. Patient adverse events will be documented on the case report forms in case they occurred and the family or advocate of the patient will be informed. In case of clinical relevant adverse events appropriate clinical action will be taken.
As the procedure does not affect the patient management, there is no need to provide any specific medical care related to the trial. Patients will receive

the relevant clinical care related to their clinical management, without any consideration to their participation in the trial. Data integrity will be verified by the company*s representative to ensure that there is no missing, unused, and spurious data.

Procedure lumbar punction:
This is a routine procedure done several times per day in hospital. The patient is usually placed in a left lateral position with their neck bent in full flexion and knees bent in full flexion up to their chest,The area around the lower back is prepared using aseptic technique. Once the appropriate location is palpated, A spinal needle is inserted between the lumbar vertebrae L3/L4, L4/L5 or L5/S1. The stylet from the spinal needle is then withdrawn and drops of cerebrospinal fluid are collected. The opening pressure of the cerebrospinal fluid will be taken during this collection by using a simple column manometer. The procedure is ended by withdrawing the needle while placing pressure on the puncture site. After the procedure patient will rest for 15 minutes. The same a-traumatic spinal needle (22Gauge) and manometer will be used in every centre.

Procedure registration with the Headsense monitor:
The front-end (ear buds) will be placed on the patient head, with each sensor placed inside the patient*s ear. It is very important to tighten the headsets to the patient*s ears properly. It is also worth noting that there is a right and left headset. There are three headset ear tips, which come in three sizes. They are used in order to ensure full adherence of the headset to the ear canal. The most suitable ear tip for the patient should be used in order to allow a good quality of signal transfer. While placing the headset in the ear, the headset should be first placed in an axial position in which the headset*s wire is perpendicular to the patients* spine. Then, the headset should be turned 90 degrees, so the headset*s wire will be perpendicular to the eyes.

Study burden and risks

As the device is non-invasive and radiation free, it has a very low risk. On the other hand the benefits that can be achieved from using a non-invasive and cost effective ICP monitor are very significant for improving future patient care and management. Therefore this trial offers a very low risk with a potential for high benefit should the technology be validated and be used in daily practice.

Safety information
So far the device has been tested on >100 patients without any negative side effects. The sound level is only 10Db so hearing damage is not likely. Allergic reaction caused by skin contact with the device (the parts that are attached to the skin) are taken from an off the shelf stethoscope, so this is also very unlikely to happen. The device is CE certified .

Patient load.

The patient load is very minimal. Patients undergo twice a measurement of 10 minutes prior to the lumbar puncture. Both times in the supine position with the first measurement , which the head is inclined 30 degrees and the second measurement just in supine position. . Then the treating physician will then perform a lumbar puncture according our local protocol.. Then the last measurement of 10 minutes in supine position will be performed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Male or Female in the age range of 18 years and older
-All patients who are referred for elective lumbar puncture including CSF pressure measurement

Exclusion criteria

-Local infection in the ear
-Pregnant or lactating women
-Cervical spine stenose
-Arnold-Chiari malformations
-Aquaductal stenosis or other changes causing an uneven CSF pressure between different compartments
-Mass lesions
-Current or previous craniotomy or craniectomies
-Suspection of meningitis or encephalitis

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	16-11-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL54424.028.15