

Title of the project

Near-infrared Spectroscopy (NIRS) for Intracranial Hematoma
Detection in traumatic head injury

NCT Number – Not Yet Available

Date: September 19, 2020

Format of research proposals to be submitted for ethical clearance

1 Title of the project

- Near-infrared Spectroscopy (NIRS) for Intracranial Hematoma Detection in traumatic head injury

2 Investigating team with contact details (Mobile number of one or more investigators is a must)

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- Co-Investigator 1: Dr. SUBHAS KONAR, Asst. Prof. of Neurosurgery, NIMHANS. Mobile Phone no. +91 9986438181
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3 Funding details

- Non-funded

4 Introduction with brief review (not more than 250 words)

- Traumatic brain injury is a common neurosurgical emergency managed in all tertiary and secondary hospital. Detecting the underlying pathology is major challenge specially for surgical cases. The outcome differs if early intervention was performed. Near Infra Red Spectroscopy [NIRS] based device will detect the hematoma at bedside or in ICU setting. Even the NIRS device can be use on trauma spot or in ambulance a with expert interpretation. Trehan, et al (1) performed the similar study in 100 patients in Indian subcontinent and found sensitivity of 58.46%, specificity of 42.86%. The negative predictive value was 35.71%. Salonia, et al (2) used the technology for detecting hematoma in 28 children and the sensitivity and specificity were 1.0 and 0.8. Brogan, et al (3) performed a metanalysis and reported sensitivity of 78% and specificity of 90 with a negative predictive value of 90%. Kahraman, et al (4) used the NIRS technology for detection of epidural and subdural hematoma and they found sensitivity of 0.87. So, the overall results of detection rate of hematoma using NIRS device is contradictory. It is not the replacement of CT scan but can help in triage. So, researchers are planning to do large scale prospective study to establish the role of NIRS device in detecting intracerebral hematoma and correlate the finding with CT scan finding.

5 Statement of the problem (not more than 50 words)

- There is a need for point of care diagnostic modalities for patients with head injury. A number of devices are being tested for the same like Brainscope, Blood Biomarkers, and NIRS based devices. Currently the NIRS based devices seem to be most promising but needs validation at multiple centers.

6 Objectives of the study (not more than 100 words)

- To evaluate detection rate of intracranial hematoma using NIRS device (Bioscan Research System®, Bioscan Research, Ahmedabad, India) in hospital.
- To correlate the NIRS device finding with the Computer Tomography (CT) finding.
- To detect clinically significant intracranial hematoma using NIRS device

7 Methods - Give specific information on

a) Participants:

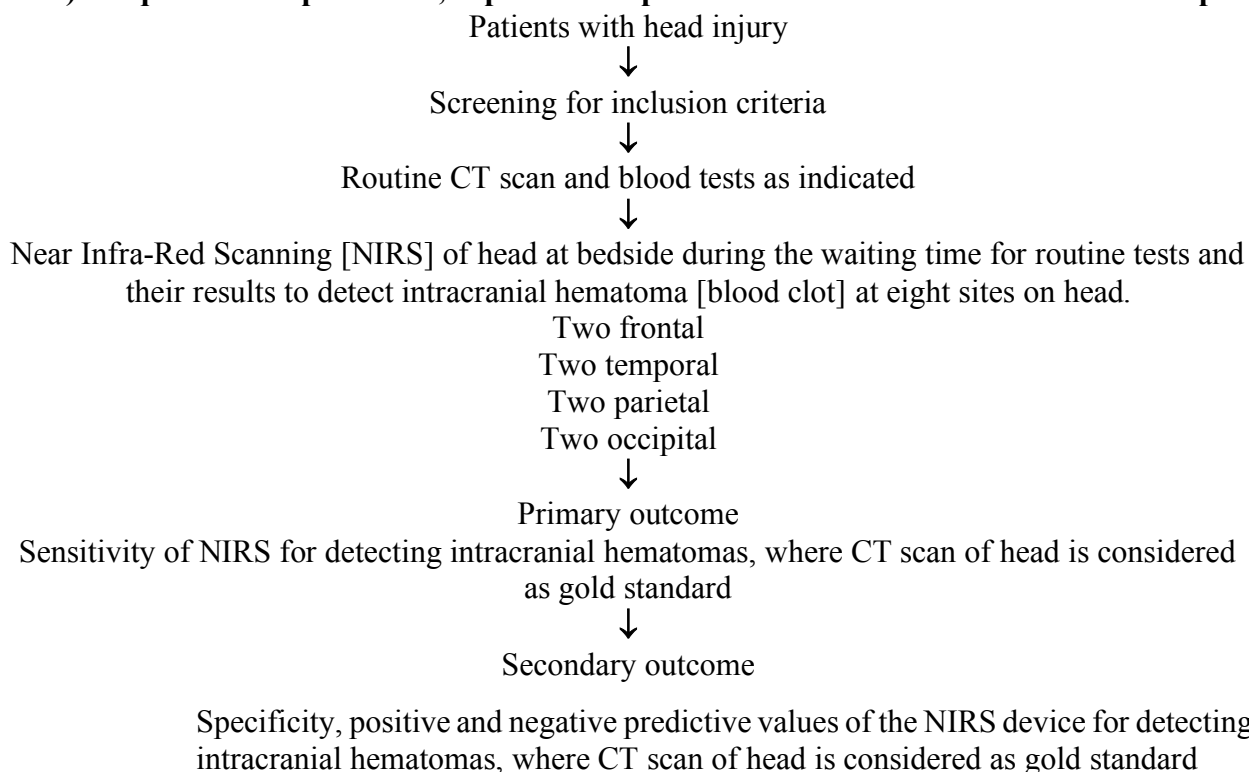
- **Age range:** 18-65 years
- **Number:** 1000
- **Gender:** All

- **Inclusion criteria:**
 - Acute head injury patients reaching our hospital.
- **Exclusion criteria:**
 - Major scalp laceration or active bleeding.
 - Significant extracranial hematoma.
 - No consent from patient's caretaker.
- **Method of selection:** Consecutive patients
- **Source from which participants would come:** Emergency Block of NIMHANS.

b) Experimental procedure:

- **Tests to be administered:** Near Infra-Red Scanning of head at bedside.
- **Time taken for testing:** Two minutes
- **Biological samples collected:** None
- **Frequency of testing/collection:** Once
- **Risks for the participants while being tested:** None
- **Methods of addressing the risk:** Not Applicable

c) Sequence of experiments, experimental procedure in brief and details of follow up.



d) List out tests that would be carried out as part of the diagnostic procedures, and tests that would be carried out as part of the research program

- **Diagnostic Tests** [all of these tests are routinely done for all patients with head trauma. None of these tests are additional for research project]
 - CT scan of head
 - Routine blood checkup for trauma patients
 - X-Ray and CT scans of other parts of body as indicated
- **Research Tests**
 - Near Infra-Red Scanning of head at bedside

e) List out the payment details - tests for which the participants pay or do not pay.

- Participants do not have to pay for research test
- Participant have to pay for tests, which are required for clinical care

8 Ethics: Please include here any ethical issues that are relevant / unique to this project. Please state whether ethics clearance has to come from any other institution. If this is a multi-center study, please state the roles / responsibilities of different institutions in the project.

- There are no ethical issues relevant/ unique to this project. The device is tested and declared safe.
- No clearance is required from other institutes.
- It is a single center study.

Important references relating to the proposal.

1. Trehan V, Maheshwari V, Kulkarni SV, Kapoor S, Gupta A. Evaluation of near infrared spectroscopy as screening tool for detecting intracranial hematomas in patients with traumatic brain injury. Med J Armed Forces India. 2018 Apr;74(2):139-142. doi: 10.1016/j.mjafi.2017.08.009. Epub 2017 Nov 27. PubMed PMID: 29692479; PubMed Central PMCID: PMC5912115.
2. Salonia R, Bell MJ, Kochanek PM, Berger RP. The utility of near infrared spectroscopy in detecting intracranial hemorrhage in children. J Neurotrauma. 2012 Apr 10;29(6):1047-53. doi: 10.1089/neu.2011.1890. Epub 2012 Jan 26. PubMed PMID: 22098538; PubMed Central PMCID: PMC3325547.
3. Brogan RJ, Kontojannis V, Garara B, Marcus HJ, Wilson MH; Near-infrared spectroscopy (NIRS) to detect traumatic intracranial haematoma: A systematic review and meta-analysis. Brain Inj. 2017;31(5):581-588. doi: 10.1080/02699052.2017.
4. Kahraman S, Kayali H, Atabey C, Acar F, Gocmen S. The accuracy of near-infrared spectroscopy in detection of subdural and epidural hematomas. J Trauma. 2006 Dec;61(6):1480-3. PubMed PMID: 17159695.