**The University of South Alabama**

**Institutional Review Board**

**PROJECT SUMMARY**

**Study Title:**

Can the cervical spine be clinically cleared in awake and alert blunt trauma patients with “distracting injuries”?

**Principal Investigator:**

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| **Support Personnel:** |  |  |
| **Institutions:**1. University of South Alabama Medical Center
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| **Sponsor/Funding Source:**None |  |  |

**Purpose:**

***Primary Objective****:*

To prospectively assess the sensitivity and efficacy of clinical examination for screening of cervical spine injury in awake and alert blunt trauma patients with concomitant “distracting injuries”.

***Secondary Objectives*:**

To evaluate missed injuries and potential complications associated with clinical clearance of the cervical spine in awake and alert blunt trauma patients with concomitant “distracting injuries”. The sensitivity and efficacy of cervical spine clinical examination will be compared between those patients with and without “distracting injuries”.

***Hypothesis for Primary Objective:***

The cervical spine can be effectively clinically cleared of injury in awake and alert blunt trauma patients with concomitant “distracting injuries”.

***Hypothesis for Secondary Objective:***

Missed cervical spine injury rate per clinical examination is very low and potential complications associated with missed cervical spine injury have minimal adverse effects.

**Background:**

The method for identification of cervical spine (c-spine) injuries in blunt trauma patients has traditionally been clinical examination in complement with radiographic evaluation. In many trauma centers, initial evaluation of blunt trauma patients for c-spine injury includes clinical examination of the neck with mandatory radiographic evaluation despite a normal clinical examination in awake and alert patients. This is likely due to the belief by many healthcare providers that clinical examination of the cervical spine is inadequate for detection of cervical spine injuries. Conversely, several prospective series have previously shown that clinical examination of the cervical spine is an extremely sensitive tool for cervical spine screening in awake and alert blunt trauma patients1-6.

Due to the high false negative rates associated with cervical spine plain radiographs, CT scanning has supplanted plain radiographs as the most common radiographic modality used to clear the cervical spine. In many centers, CT scan of the cervical spine is performed on all blunt trauma patients, regardless of findings on clinical examination7-9. However, several previously published series support cervical spine CT scanning when warranted by a positive clinical examination6, 10, 11. The Eastern Association for the Surgery of Trauma (EAST) Practice Management Guidelines supports selective use of CT scan when clinically indicated12. Clinical examination of the neck in complement with selective CT scanning has recently been shown to provide a sensitive means for determination of c-spine injury in awake and alert blunt trauma patients6, 10, 11.

The concept that “distracting injuries” negate clinical examination as a screening tool for c-spine injury in awake and alert blunt trauma patients continues to perplex clinicians, particularly those clinicians who use clinical examination as their primary screening modality. Most trauma centers and clinicians that advocate clinical examination, forgo this screening tool in the presence of distracting injuries. The issue raised is: what constitutes a “distracting injury”? The practicing clinician is left to define “distracting injury” at the bedside each time he or she is confronted with this scenario. Since its inception, the Advanced Trauma Life Support (ATLS) guidelines have advocated mandatory radiographic evaluation of the cervical spine in awake and alert blunt trauma patients with “distracting injuries”, yet, the guidelines fail to define “distracting injury”13. Recently, a prospective series from the University of South Alabama suggested that clinical clearance of the cervical spine in the presence of “distracting injuries” can be accomplished with excellent sensitivity in awake and alert blunt trauma patients14. The authors concluded that mandatory CT scan is unnecessary in awake and alert blunt trauma patients with “distracting injuries” whose cervical spine is clinically cleared.

 The purpose of this study is to prospectively evaluate a protocol that assesses the sensitivity and efficacy of clinical examination for screening of c-spine injuries in the awake and alert blunt trauma patient with “distracting injuries”.

**Concise Summary of Project:**

This will be a prospective study at USAMC and other centers that assesses blunt trauma patients with “distracting injuries” who are awake and alert. These patients will undergo clinical examination of the cervical spine. Following documentation of the cervical spine clinical examination, all patients will undergo CT Scan of the cervical spine and results of the clinical examination and cervical spine CT Scan will be compared.

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| **Primary Outcome** | **Definition** |
| Cervical spine injuries successfully identified by clinical examination in patients with “distracting injuries”. | Cervical spine injury identified on CT scan with positive clinical examination for cervical spine injury. |
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| **Secondary Outcomes** | **Definitions** |
| Missed cervical spine injuries by clinical examination in patients with “distracting injuries”. | Cervical spine injury identified on CT scan with negative clinical examination for cervical spine injury |
| Missed cervical spine injuries requiring surgical intervention in patients with “distracting injuries”. | Cervical spine injuries identified on CT scan with negative clinical examination for cervical spine injury with the cervical spine injury requiring surgical intervention. |
| Missed cervical spine injuries treated with cervical collar in patients with “distracting injuries”. | Cervical spine injuries identified on CT scan with negative clinical examination for cervical spine injury with the cervical spine injury requiring management with cervical collar. |
| Missed cervical spine injuries that require no specific therapy in patients with “distracting injuries”. | Cervical spine injuries identified on CT scan with negative clinical examination for cervical spine injury with the cervical spine injury requiring no specific treatment |
| Missed cervical spine injuries in patients who do not have “distracting injuries”. | Cervical spine injury identified on CT scan with negative clinical examination for cervical spine injury |
| Potential cost-savings if cervical spine CT Scan not performed | Calculated savings in revenue by obviating CT scan in those patients with negative clinical examination |
| Potential reduction in radiation exposure if cervical spine CT Scan not performed | Determination of reduction in radiation exposure for patients who have cervical spine cleared by clinical examination rather than CT scan |
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**Study Procedures:**

This is a prospective study that enrolls blunt trauma patients who are awake and alert with GCS > 14. Following clinical examination of patients who fit inclusion criteria, patients will undergo CT Scan of the cervical spine. Consent will be waived as CT Scan is standard of care in all participating hospitals to identify cervical spine injury. Results of cervical spine clinical examinations will be documented in a data collection form. Patients will be informed that they have been entered in a study. **See Fig. 1**

**Criteria for Inclusion and Exclusion of Subjects:**

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| **Inclusion Criteria** | **Rationale** |
| 1. Awake and alert blunt trauma patients with GCS > 14  | Population of interest. |
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| **Exclusion Criteria** | **Rationale** |
| 1. Age less than 14 years | Vulnerable population |
| 2. Glasgow Coma Score < 14 | Inadequate neurologic examination |
| 2. Pregnant patients | Vulnerable population |
| 4. Death in the ED | These patients will not have survived long enough to undergo CT Scan |

**Sources of Research Material:**

USAMC and other participating trauma centers will prospectively collect data on all awake and alert blunt trauma patients with GCS > 14. All patient-related data will be obtained prospectively and collected during routine clinical care. Specific data to be collected will be demographic data, clinical data from cervical spine clinical examination and patient assessment for all injuries sustained, results of cervical spine CT scan and neurosurgical disposition of cervical spine injuries. Technical details of board-certified radiologist interpretations of cervical spine CT scan will also be gathered. Finally, clinical disposition of patients with missed cervical spine injuries will be documented.

**Recruitment Methods and Consenting Process:**

USAMC and other participating trauma centers will prospectively enter blunt trauma patients in the study following patient admission to the emergency room. The research involves no more than minimal risk to the subjects, AND 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects, AND 3) the research can be practicably carried out with the waiver or alteration because standard of care is not deviated from during the course of this research, AND 4) whenever appropriate, the subjects will be provided with additional pertinent information after participation. Further, an expedited review will be requested pursuant to Category 5: The research will involve materials (data, documents, records, or specimens) that have been collected, or will be collected solely for *non-research* purposes such as medical treatment or diagnosis. The PHI will pertain to data collected during the course of the delivery of the standard of care. The only vulnerable populations to be included will be minors between ages 14 to 18 years. It is felt necessary to include them as they are frequently victims of blunt trauma. The protections already being applied to all patients will be applied to them as well.

**Potential Risks:**

Given that care provided during the course of this study is considered standard of care, the greatest risk to patients is that of a breach of confidentiality. This risk will be minimized through the data management procedures outlined below in “Procedures to Maintain Confidentiality”.

**Subject Safety and Data Monitoring:**

Since this is a prospective study that does not breach the standard of care, it poses no more than minimal risk to participants, and therefore a data safety monitoring plan will not be instituted.

**Procedures to Maintain Confidentiality:**

The data sheet will contain the patient’s name and PHI pertaining only to the study. The data sheets will maintained at the respective study site in a locked filing cabinet.

The data sheets from all institutions will be entered into an electronic file and these files will be sent electronically via email to the PI at USAMC. Electronic files will be kept on a desktop of the individual institutional PIs office computer which is password protected and kept in a locked office. All data in that file will only be available to the PI. The PI at USAMC will maintain data from USAMC and data sent from other institutions. Data at USAMC will be maintained on the PI’s office computer and will be password protected and kept in a locked office. Upon completion of the data analysis, all electronic files at all institutions will be deleted and hard copies of data collection forms will be shredded.

**Potential Benefits:**

If this study concludes that CT scans are unnecessary in awake and alert patients with “distracting injuries”, considerable cost savings and reduction in radiation exposure can be realized in this patient population.

**Biostatistics:**

*Primary objective:*

Sensitivity, specificity, negative predictive value, etc. will be determined for clinical examination of the cervical spine in patients with “distracting injuries”.

*Secondary objective:*

Missed cervical spine injury rates for awake and alert patients with “distracting injuries” will be compared to those of patients without distracting injuries using Student’s t-test. Significance will be set at p < 0.05.

*Power analysis:*

Power analysis based on the University of South Alabama’s previous experience suggests that 2850 patients with distracting injuries and an equal number without distracting injuries will allow detection of a difference in sensitivity of 1%. For the purposes of this study, acceptance of the null hypothesis will be attained if the sensitivity of cervical spine clinical examination with distracting injuries is within 1% of patients without distracting injuries. Interim analysis will be performed at 25, 50 and 75% enrollment to assess consistency between institutions and need for continued enrollment.

**References:**

1. Roberge RJ, Wears RC, Kelly M, et al. Selective application of cervical spine radiography in alert victims of blunt trauma: a prospective study. J Trauma. 1988;28:764-788
2. Velmahos GC, Theodorou D, Tatevossian R, et al. Radiographic cervical spine evaluation in the alert symptomatic blunt trauma victim; much ado about nothing? J Trauma. 1996;40:768-774
3. Gonzalez RP, Freed PO, Bukhalo M, Holevar MR, Falimirski ME. Role of clinical examination in screening for blunt cervical spine injury. J Amer coll surg. 1999;189:152-157
4. Hoffman JR, Mower WR, Wolfson AB, et al. Validity of a set of clinical criteria to rule out injury to the cervical spine in patients with blunt trauma. N eng J Med. 2000;343:94-99
5. Stiell IG, Wells GA, Vandemheen KL, et al. The Canadian C-spine rule for radiography in alert and stable blunt trauma patients. JAMA. 2000;286:1841-1848
6. Gonzalez RP, Cummings GR, Phelan HA, Bosarge PL, Rodning CB. Clinical examination in complement with computed tomography scan: an effective method for identification of cervical spine injury. J Trauma. 2009; 67:1297-1304
7. Blackmore CC, Mann FA, Wilson AJ. Helical CT in the primary trauma evaluation of the cervical spine: an evidence –based approach. Skeletal radiology. 2000; 29(11):632-639
8. Grogan EL, Morris JA, Diffus RS, Moore DE, et al. Cervical spine evaluation in urban trauma centers: lowering institutional costs and complications through helical CT scan. J Am Coll Surg. 2005; 200(2):160-165
9. Antevil JL, Sise MJ, Sack DI, et al. Spiral computed tomography for the initial evaluation of spine trauma: a new standard of care. J Trauma. 2006; 61(12): 382-387
10. Sanchez B, Waxman K, Jones T, et al. Cervical spine clearance in blunt trauma: evaluation of a computed tomography-based protocol. J Trauma. 2005;59(1): 179-183
11. Griffen MM, Frykberg ER, Kerwin AJ, Schinco, et al. Radiographic clearance of blunt cervical spine injury: plain radiograph or computed tomography scan. J Trauma. 2003; 55(2): 222-226
12. Como JJ, Diaz JJ, Dunham CM, Ad Hoc Committee. Practice management guidelines for identification of cervical spine injuries following trauma-update from the Eastern Association for the Surgery of Trauma Practice Management guidelines Committee; 2009; [www.east.org](http://www.east.org).
13. American College of Surgeons. ATLS Student Manual: Spine and Spinal cord Trauma, 7th ed. Chicago, American College of surgeons, 2007.
14. Rose MK, Rosal LM, Gonzalez RP, Rostas JW, et al. Clinical clearance of the cervical spine in patients with distracting injuries: It is time to dispel the myth. J Trauma. 2012; 73 (2): 498-502