‘CHIP REfinement STudy (CREST)’. Prospective refinement study of the CHIP (CT in Head Injury Patients) prediction rule for patients with minor head injury.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22644

Source
Nationaal Trial Register

Brief title
CREST

Health condition

Minor head injury
mild Traumatic Brain injury
traumatic Intracranial Haemorrhage
Licht Traumatisch Hoofd/Hersenletsel

Sponsors and support

Primary sponsor: Medical Centre Haaglanden, department of emergency medicine, The Hague
Source(s) of monetary or material Support: St Jacobus Stichting, The Hague

Intervention

Outcome measures

Primary outcome

• Refine/modify the CHIP prediction rule to enhance efficiency and determine the sensitivity, specificity and predictive values of the modified CHIP prediction rule for both traumatic intracranial lesions on CT scan and neurosurgical lesions on CT scan.

Secondary outcome

• To prospectively validate the CHIP prediction rule for the use of head CT in patients with minor head injury.
This entails determining sensitivity, specificity, and predictive values in predicting the presence versus absence of a traumatic intracranial lesion on the CT scan.

• Determine sensitivity, specificity, and predictive values of the original CHIP prediction rule in predicting the presence of a traumatic intracranial lesion on the CT scan that necessitates neurosurgical intervention within 30 days after trauma.

• Determine which of the collected potential risk factors are independent risk factor for traumatic intracranial lesions on CT scan.

• For self referred patients at the ED: determine the sensitivity, specificity and predictive values of the referral criteria as defined by the Netherlands General Practitioners society (NHG) for both traumatic intracranial lesions on CT scan and neurosurgical intervention.

• Determine if any admitted patients deteriorate during admission (deteriorated GCS; new/progression of traumatic findings on head CT; neurosurgical intervention).

• Determine if any patients return with traumatic intracranial lesions that were not identified on the initial CT-head and determine the interval between trauma and the initial CT-head.

• For patients with traumatic intracranial lesions on CT the Extended Glasgow Outcome Scale (GOSE) at 3 months will be assessed.

• Determine if the protein S100B is a reliable marker for intracranial findings on CT in patients with minor head injury. (substudy only in MCH-Bronovo)

This entails determining sensitivity, specificity, and predictive values in predicting the presence versus absence of a traumatic intracranial lesion on the CT scan.

Study description

Background summary

Rationale: Intracranial complications after minor head injury are infrequent (<10%), but are potentially life threatening and occasionally (<1%) require neurosurgical intervention. Computed tomography (CT) is the imaging modality of choice for fast and reliable diagnosis of intracranial complications of head injury. To enhance the selective use of CT in minor head trauma patients and to limit practice variation several decision rules and guidelines for minor head injury have been developed. In The Netherlands the CBO guideline, which is based on the CT in Head Injury Patients (CHIP) prediction rule, is generally used. This prediction rule is applicable to (almost) all adult patients with blunt head injury. In the derivation study the CHIP prediction rule had a sensitivity of 100% for neurosurgical intervention and a sensitivity of 94-96% for intracranial traumatic CT findings. To date no validation study has been done.

A recent study however showed that both CT-ratio and hospitalization increased after introduction of the CBO guideline. Another concern about the CHIP prediction rule is that it has not been externally validated and not tested in non-level I trauma centers or non-university hospitals. The Hypothesis of the CREST study are:

1. Refinement of the CHIP prediction rule will lead to a more efficient use of head CT in patients with minor head injury

2. The CHIP prediction rule is a safe prediction tool in regard to predicting the absence of intracranial lesions on CT scan after minor head injury.

Objective: Primary objective of the CREST is to refine the CHIP prediction rule for the use of head CT in patients with minor head injury.

Study design: Multicenter prospective noninterventional cohort study

Study population: Patients 16 years and older with minor head injury

Intervention (if applicable): Not applicable

Main study parameters/endpoints: Any intracranial traumatic lesion on CT scanning is considered a positive outcome.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Since this is a noninterventional study no specific risks are associated with participation. CT-scans will be made according to the CBO/CHIP guideline, this is currently standard care. No additional visits are needed. Only patients with intracranial traumatic findings on CT will be asked permission for telephonic contact after three months to fill out a short questionnaire (GOSE questionnaire)

Study objective

Refinement of the CHIP prediction rule will lead to a more efficient use of head CT in patients with minor head injury

Study design

Not applicable

Intervention

CT scan of the head

S100B blood sample

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Patients 16 years and older and

• Blunt trauma to the head in the last 24 hours and

• Fulfill the definition of minor head/brain injury as defined in the Dutch guideline:

o Glasgow Coma Scale (GCS) of 13-15

o In case of posttraumatic loss of consciousness: no more than 30 minutes

o In case of posttraumatic anterograde amnesia: no more than 24 hours

• A head CT is made to rule out traumatic intracranial lesions (according to current hospital guidelines)

• Have at least one risk factor (minor or major criteria in CBO guideline):

o Pedestrian or cyclist versus vehicle

o Ejected from motor vehicle

o Vomiting

o Signs of skull fracture

o GCS score <15 on presentation

o Posttraumatic amnesia

o GCS deterioration

o Coumarin or heparin (LMWH) use

o Posttraumatic seizure

o Age ≥ 40

o Fall from any elevation

o Focal neurologic deficit

o Loss of consciousness

o Persistent anterograde amnesia

o Visible injury to the head, excluding the face (without signs of fracture)

o Suspicion of intracranial injury after focal “high impact” injury

o Use of antiplatelet drugs

o Use of New/Direct Oral Anticoagulants NOAC’s/DOAC’s

o Signs of intoxication with alcohol or drugs

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Contraindications for CT scanning

• Patients with concurrent injuries that preclude CT scanning

• Only superficial injury to the face. The face is defined as the area of the head from (including) the eyebrows to the chin (including).

• No head CT-scan is made

• Patients transferred from other hospitals

• Consecutive ED visit for the same trauma

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2016
Enrollment:	2703
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL5300
NTR-old	NTR5409
Other	: VOLGT

Study results