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

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22644

Bron
Nationaal Trial Register

Verkorte titel
CREST

Aandoening

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

Ondersteuning

Primaire sponsor: Medical Centre Haaglanden, department of emergency medicine, The Hague
Overige ondersteuning: St Jacobus Stichting, The Hague

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Doel van het onderzoek

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

Onderzoeksopzet

Not applicable

Onderzoeksproduct en/of interventie

CT scan of the head

S100B blood sample

Contactpersonen

Publiek

Koningsplein 17

Crispijn van den Brand
Den Haag 2518JE
The Netherlands
0651728689

Wetenschappelijk

Koningsplein 17

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2016
Aantal proefpersonen:	2703
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5300
NTR-old	NTR5409
Ander register	: VOLGT

Resultaten