Fresh Intravenous Blood Samples for TBI Diagnostic Assay Development with Philips Point of Care System (FIRST DOWN)*

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The purpose of this study is to collect fresh whole blood from subjects who have had a suspected head injury (Glasgow Coma Scale score 9-15), for use during the early phase of development of an investigational diagnostic assay platform (Philips...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON45901

Source
ToetsingOnline

Brief title
FIRST DOWN

Condition

- Other condition

Synonym
Brain damage, Traumatic Brain Injury

Health condition

traumatisch hersenletsel

Research involving

Human

Sponsors and support

Primary sponsor: Banyan Biomarkers, Inc
Source(s) of monetary or material Support: Banyan Biomarkers Inc,Ministerie van Defensie van Amerika

Intervention

Keyword: bloodsamples, brain injury, Falls

Outcome measures

Primary outcome

The purpose of this study is to collect fresh whole blood from subjects who have had a suspected mild to moderate head injury (Glasgow Coma Scale score 9-15), for testing and evaluation of an investigational diagnostic assay platform (Philips Minicare POC). The fresh whole blood samples collected in this study will be used to help verify that both UCH-L1 and GFAP can be detected with the Philips Minicare POC diagnostic test platform. The procedures for testing specimens on the Philips Minicare POC, including the criteria for demonstrating proficiency of assay performance, will be described in a separate protocol maintained by the Sponsor. If successful, a clinical study will be designed and conducted to validate that the Philips Minicare POC diagnostic test meets the proposed Intended Use.

Secondary outcome

NA

Study description

Background summary

Traumatic brain injury (TBI) is a significant public health problem representing a potentially catastrophic and debilitating medical emergency. The current standard of care has significant limitations, and many patients who suffer TBI do not receive medical care because the effects of TBI are often not immediately or outwardly visible. There exists an unmet medical need to improve the diagnosis and management of TBI. A biomarker test for TBI has the potential to greatly improve the triage and management of head injured patients, and at the same time, prevent the unnecessary use of neuroimaging and radiation exposure to patients.

Study objective

The purpose of this study is to collect fresh whole blood from subjects who have had a suspected head injury (Glasgow Coma Scale score 9-15), for use during the early phase of development of an investigational diagnostic assay platform (Philips Minicare POC).

Study design

This is a prospective study that will enroll up to 500 subjects over a period of 2 years at up to 5 centers who present to the health care facility (HCF) or Emergency Department (ED) with suspected head injury and an initial GCS of 9-15

Study burden and risks

The study poses negligible risk to subjects. The collection of specimens is minimally invasive, and largely consists of standard specimen collection procedures used in the evaluation of TBI. These do not pose a health hazard to the subject. The informed consent form will describe the potential risks to the subjects.

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

1. The Subject is at least 18 years of age at screening.
2. The Subject has presented to a Health Care Facility (HCF) or Emergency Department (ED) with a suspected traumatically induced head injury, as a result of insult to the head from an external force.
3. The Subject has a Glasgow Coma Scale score of 9-15 at the time of Informed Consent.
4. The venous blood sample is collected no later than 12 hours from the time of head injury.
5. The Subject or their Next of Kin is willing to undergo the Informed Consent process prior to enrollment into this study

Exclusion criteria

1. Participating in any other interventional, therapeutic clinical study (an observational study would be acceptable).
2. Time of suspected head injury cannot be determined.
3. Venipuncture not feasible (i.e., skin integrity compromised at the venipuncture sites, blood vessel calcification (i.e., IV drug users, advanced atherosclerosis) both upper limbs missing (congenital or amputee)).
4. Blood transfusion after head injury, and prior to study blood draw
5. Blood donation within 1 week of study enrollment.
6. The subject is a female who is pregnant or lactating.
7. The Subject is otherwise determined by the Principal Investigator to be an unsuitable candidate for participation

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-06-2016
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	26-04-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-10-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-01-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-02-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	20-04-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
ClinicalTrials.gov	NCT02541123
CCMO	NL56548.091.16