

Head and traumatic brain injury in England: a cohort study

Submission date 08/11/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/11/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/12/2023	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Head injuries are common, and result from a physical trauma to the head. Traumatic brain injuries (TBI) are due to head injuries, and so less common. A person can bump their head without injuring their brain. TBI can be mild, moderate or severe, but even mild TBI can result in clinically significant disordered cerebral function and new symptoms, including cognitive deficits, headaches, and depression. Symptoms in mild TBI can persist for months or even years, and lead to inability to return to normal function such as work. Severe TBI can lead to total dependency for all functions.

The difference between head injuries and TBI is important for health resource planning. People cannot be diagnosed with TBI unless they see a health professional following a head injury. This will be in an Emergency Department (ED), in a general practice, or in the case of sports concussion (a subgroup of mild TBI) at the side of the pitch. The number and incidence of head injuries and TBI is therefore important to know.

This study is designed to identify the population incidence of head injury and the rate of traumatic brain injury, stratified by geographic location, age, gender, and ethnicity. Head injuries and traumatic brain injuries are thought to be common but the data available are either 50 years out of date or based on small and limited cohorts. Accurate data would enable appropriate health resource allocation which would result in improved patient outcomes.

Who can participate?

The study population contains all patients that attended an ED in England in 2019.

What does the study involve?

Gathering of data regarding head injury from four linked data sets; ECDS, DIDS, APC-HES and ONS-mortality.

What are the possible benefits and risks of participating?

This study will utilize nationally available data sets for analysis and consequently presents no clinical risk to patients. Pseudonymised records will be analysed by an a priori plan.

Where is the study run from?
Barts Health NHS Trust (UK)

When is the study starting and how long is it expected to run for?
March 2021 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ben Bloom, ben.bloom@nhs.net
Imogen Skene, i.skene@nhs.net

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

301676

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 301676

Study information

Scientific Title

Epidemiology of head injury and traumatic brain injury in England: a cohort study

Acronym

TBI in England

Study objectives

The primary objective of the study is to describe the population incidence of attendance to the ED with head injury amongst the population of England.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/01/2022, HRA and Health and Care Research Wales (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net, HCRW.approvals@wales.nhs.uk), ref: 22/HRA/0365

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not applicable (retrospective study)

Health condition(s) or problem(s) studied

Determine population incidence of head injury and traumatic brain injury, and identify associated factors.

Interventions

This study will utilise data from four linked data sets; ECDS, DIDS, APC-HES and ONS-mortality.

A head injury cohort will be defined using ECDS chief complaint and diagnosis SNOMED CT values, and DIDS radiology values. Outcomes of traumatic brain injury, intracranial haemorrhage, neurosurgery, and mortality will be measured. Associated factors including age, sex, ethnicity, language, accommodation status, geographical region, index of multiple deprivation, injury characteristics and injury place will be assessed.

Intervention Type

Other

Primary outcome measure

Incidence of head injury attendance to Emergency Departments amongst the population of England measured using data from four linked data sets; ECDS, DIDS, APC-HES and ONS-mortality

Secondary outcome measures

Measured using data from four linked data sets; ECDS, DIDS, APC-HES and ONS-mortality:

1. Population incidence of TBI amongst the population of England
2. Incidence of head injury amongst the population of people that attend EDs in England
3. Incidence of types of TBI by anatomical classification
4. Incidence of surgery for TBI
5. Rate of death due to TBI
6. The association (if any) with TBI of independent variables including age, sex, ethnicity and index of multiple deprivation

Overall study start date

25/03/2021

Completion date

31/12/2024

Eligibility**Key inclusion criteria**

The study period is 01/11/2018 to 29/02/2020 and the population of interest includes all patients that attended an ED in England in 2019

Participant type(s)

Patient

Age group

All

Sex

Both

Target number of participants

25 million ED attendances, of which previous estimates of 1.4 million patients have head injuries.

Key exclusion criteria

Since this is a study aiming to identify the national population incidence of head injury, the national rate of ED attendance for head injury, and the association (if any) of possible predictors with TBI including age, sex, ethnicity and socio-economic group, all ED attendances in England will be the baseline population, and consequently there are no exclusion criteria within the study period.

Date of first enrolment

01/11/2018

Date of final enrolment

29/02/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Barts Health NHS Trust

The Royal London Hospital

80 Newark Street

London

United Kingdom

E1 2ES

Sponsor information

Organisation

Barts Health NHS Trust

Sponsor details

Joint Research Management Office
Research Services for Barts Health NHS Trust and Queen Mary University
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Sponsor type

Hospital/treatment centre

Website

<http://www.bartshealth.nhs.uk/>

ROR

<https://ror.org/00b31g692>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the data being protected and released into a prespecified governed environment.

IPD sharing plan summary

Not expected to be made available