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Head and traumatic brain injury in England: a cohort study

Submission date
08/11/2022

Recruitment status
No longer recruiting

Registration date
10/11/2022

Overall study status
Completed

Last Edited
07/12/2023

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 Head injuries and traumatic brain injuries are thought to be common but the data available are either 50 years out of date or based on small and limited cohorts.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. Psedonymised 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 Decmeber 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ben Bloom, ben.bloom@nhs.net
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Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
301676

Protocol serial number
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

Study type(s)
Other

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
All

Sex
All

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
United Kingdom

England

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
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E1 2ES

Sponsor information

Organisation
Barts Health NHS Trust

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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