

Long-term results of major trauma in Taiwan

Submission date 02/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/12/2023	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

The long-term result of major trauma is mostly unknown until the present day. The traditional trimodal distribution of deaths was first described in 1982, implying that death due to injury occurs in three peaks. The first peak occurs within seconds to minutes of injury, the second peak occurs within minutes to several hours following injury, and the third peak occurs several days to weeks after the initial injury. However, research regarding the long-term results is scarce. The aim of this study is to better define the long-term outcome of major trauma patients, including survival, medical expenses, and individual economic impact.

Who can participate:

Patients aged 18 to 70 years sustaining major trauma in the period of January 2003 to December 2007 from the National Health Insurance Research Database (NHIRD)

What does the study involve?

This study involves a 10-year long-term follow-up from the NHIRD data. Information including the patient's age, injury types, admission length, insurance amount, medical expense, and survival will be analyzed.

What are the possible benefits and risks of participating?

This is a retrospective observational database study. There are no potential benefits and risks for the participants.

Where is the study run from:

The Health and Welfare Data Science Center (Taiwan)

When is the study starting and how long is it expected to run for?

May 2020 to April 2021

Who is funding the study?

1. Chang Gung Memorial Hospital, Linkou (Taiwan)
2. Ministry of Science and Technology (Taiwan)

Who is the main contact?

Dr Ling-Wei Kuo, m0102@cgmh.org.tw

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Ling-wei Kuo

ORCID ID

<http://orcid.org/0000-0001-6489-3723>

Contact details

No.5, Fuxing St., Guishan Dist.

Taoyuan City

Taiwan

333

+886 (0)975361358

m0102@cgmh.org.tw

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

The long-term results of major trauma patients: a nationwide cohort study from Taiwan's national health insurance database

Study objectives

The long-term result of major trauma is mostly unknown until the present day. The traditional trimodal distribution of deaths was first described in 1982, implying that death due to injury occurs at three peaks. The first peak occurs within seconds to minutes of injury, the second peak occurs within minutes to several hours following injury, and the third peak occurs several days to weeks after the initial injury. However, research regarding the long-term results is scarce. The purpose of this study is to better define the long-term outcome of major trauma patients, including aspects of survival, medical expense, and individual economic impact.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/04/2020, Chang Gung Medical Foundation IRB (Tung Hwa North Road, Taipei, 199, Taiwan; +886 (0)3 3196200 ext #3705~3708; irb1@cgmh.org.tw), ref: Reference number not provided

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital, Internet/virtual

Study type(s)

Other, Quality of life

Participant information sheet

Not applicable

Health condition(s) or problem(s) studied

Major trauma

Interventions

The researchers will retrospectively collect data of adult patients aged 18 to 70 years sustaining major trauma (injury severity score, Injury Severity Score [ISS] ≥ 16) in Taiwan in the period of January 2003 to December 2007 from the National Health Insurance Research Database (NHIRD) under the NHIRD regulation, and perform a 10-year long-term follow from the NHIRD data. The NHIRD is a de-identified database that contain all the procedure and expense in the National Health Insurance system. The researchers expect to enrol 25000 patients treated with major trauma as the experimental group and 50000 patients from the general population as the control group. Information including the patient's age, injury types, admission length, insurance amount, medical expense, and survival will be analyzed. Basic demographics and short-term outcomes were analyzed, and the 10-year long-term outcome was calculated. After the analysis, the researchers will establish long-term results for major trauma patients, thus understanding the impact of major trauma in Taiwan from medical, social, and economic aspects.

Intervention Type

Other

Primary outcome measure

10-year cumulative survival rate. Survival is defined as the death date recorded in the NHIRD. Patients were further stratified into two groups: short survival (SS) and long survival (LS). SS was defined as survival < 1 year after being discharged from the index admission, whereas LS was defined as survival ≥ 1 year after being discharged from the index admission.

Secondary outcome measures

1. Long-term nursing care (LTC). LTC was defined as being admitted to a chronic ward or having skilled nursing care in the outpatient fashion 1 year after the discharge from the index admission. The record of chronic ward admission could be found in the Inpatient Expenditures by Admissions file in the NHIRD, and the record of skilled nursing care could be found in the Ambulatory Care Expenditures by Visits file in the NHIRD.

2. Post-injury income. To define the income level of the target population, the researchers first examined the NHI payroll bracket. The payroll bracket can be divided into six categories. Categories 1, 2, and 3 consist of the people who have registered sources of income, including all the employees, employers, self-employed workers who belong to occupational unions. Category 4 belongs to military servicemen/women and those who are serving sentences in a penitentiary. Categories 5 and 6 are welfare-associated, mainly comprising members of low household income and veterans. For categories 1 to 3, the monthly income is equivalent to the insurance amount, but the premiums of the beneficiaries in categories 4 to 6 were calculated differently and did not reflect the actual income. Therefore, categories 4 to 6 were ruled out from the analysis. The researchers then considered the ID number of the insured. If the personal ID number matched the insured ID number, it indicated that this person was an actual working person with registered income. If the ID numbers did not match, it implied that this person was fostered by another actual working person, and he or she had no registered income. In conclusion, the researchers identified their target population by locating the actual working people in categories 1 to 3 from the payroll bracket; thus, their insurance amount reflected their income level. The median preinjury monthly income of the enrolled patients was 640 US dollars (USD), hence preinjury monthly income ≤ 640 USD was classified as low income, whereas > 640 USD was considered high income.

3. Return to work (RTW). The researchers recorded the preinjury insurance amount of actual working people identified from categories 1-3. One month after discharge, patients were examined again. Those who moved to categories 4-6 were placed in the non-RTW group, indicating loss of work ability due to reliance on welfare or imprisonment. If their category remained in 1-3, but the insurance amount dropped to zero, it suggested that they no longer had registered income but were insured under another actual working person. These patients were also placed in the non-RTW group. Patients were placed in the RTW group only if they remained in categories 1 to 3 and continued to have registered income.

Overall study start date

01/05/2020

Completion date

30/04/2021

Eligibility

Key inclusion criteria

This retrospective observational study included all patients aged 18 to 70 years with major trauma in Taiwan from January 2003 to December 2007

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

25000

Total final enrolment

23442

Key exclusion criteria

1. <18 years old or >70 years old
2. ISS <16
3. Patients who had previously received a catastrophic illness certificate (CIC) for other serious conditions

Date of first enrolment

01/01/2003

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Taiwan

Study participating centre

Chang Gung Memorial Hospital, Linkou

No. 5, Fuxing St., Guishan Dist.

Taoyuan City

Taiwan

333

Sponsor information

Organisation

Linkou Chang Gung Memorial Hospital

Sponsor details

No.5, Fuxing St., Guishan Dist.
Taoyuan City
Taiwan
333
+886 (0)3 3281200
m0102@cgmh.org.tw

Sponsor type

Hospital/treatment centre

Website

<http://www1.cgmh.org.tw/branch/lnk/e/index.aspx>

ROR

<https://ror.org/02dnn6q67>

Funder(s)

Funder type

Government

Funder Name

Ministry of Science and Technology, Taiwan

Alternative Name(s)

Ministry of Science and Technology, R.O.C. (Taiwan), Ministry of Science and Technology of Taiwan, MOST

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Taiwan

Funder Name

Chang Gung Memorial Hospital

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/05/2024

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study are not publicly available due to the patient confidentiality restrictions of the NHIRD but are available from the NHIRD on reasonable request.

IPD sharing plan summary

Not expected to be made available