

Hepatitis A vaccination coverage amongst people with Chronic Liver Disease in England (HEALD): protocol for a retrospective cohort study

Submission date 11/09/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/01/2025	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Hepatitis A outbreaks in the United Kingdom are uncommon. Most people develop mild-to-moderate symptoms that resolve, without sequelae, within months. However, in high-risk groups, including those with underlying chronic liver disease, hepatitis A infection can be severe, with higher risk of mortality and morbidity.

The UK's public health body, the Health Security Agency and the English guidelines organisation, the National Institute of Health and Care Excellence, recommend pre-exposure hepatitis A vaccination given as two doses to people with chronic liver disease, regardless of its cause. There are currently no published reports of vaccination coverage in people with chronic liver disease in England, or internationally.

The study aims to describe hepatitis A vaccination coverage in adults with chronic liver disease in a UK primary care setting. To compare liver disease aetiology, sociodemographic characteristics and comorbidities in people who are and are not exposed to hepatitis A vaccine.

Who can participate?

Data used for the study will include all the individuals in England.

What does the study involve?

During the study GP data will be retrospectively analysed to get an understanding of hepatitis A vaccination coverage in adults with chronic liver disease in a UK primary care setting, comparing liver disease aetiology, sociodemographic characteristics and comorbidities in people who are and are not exposed to hepatitis A vaccine.

What are the possible benefits and risks of participating?

The results of the study will give a better understanding about how to administer the hepatitis A vaccine to people with chronic liver disease in the English population in the future.

Where is the study run from?

Nuffield Department of Primary Health Care Sciences of the University of Oxford (UK)

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

March 2022 to August 2024

Who is funding the study?

GlaxoSmithKline (Belgium)

Who is the main contact?

Prof. Simon de Lusignan, simon.delusignan@phc.ox.ac.uk

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

GSK ISS: 14309

Study information

Scientific Title

Hepatitis A vaccination coverage amongst people with Chronic Liver Disease in England (HEALD): protocol for a retrospective cohort sentinel network database study

Acronym

HEALD

Study objectives

This study fills this gap reporting ehpatitis A (Hep A) vaccine coverage in people with chronic liver disease (CLD), with a focus on whether there are disparities as to which people with CLD receive Hep A vaccination.

The study aim is to report Hep A vaccination coverage in people with CLD in English primary care and the predictors of receiving a single dose or full vaccination course. With the folowing objectives:

1. To report Hep A vaccination coverage in people with CLD by:
 - a. Sociodemographic characteristics (e.g. age, gender, ethnicity, deprivation, obesity, smoking, alcohol consumption)
 - b. CLD disease type (e.g. alcholic liver disease, chronic hepatitis B and C, Non alcoholic fatty liver disease).

- c. CLD complications (e.g. renal disease, ascites, liver failure and transplant, cardio-metabolic disease)
 - d. Comorbidities and exposures (e.g. Cambridge Multimorbidity Score (CMMS), bile duct and colon cancers, at least three doses of COVID-19 vaccine, flu vaccination).
2. To report the predictors of one- and two-doses of Hep A vaccination in people with CLD.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 09/06/2022, Central University Research Ethics Committee (CUREC) at the University of Oxford (Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44 1865 616577; ethics@medsci.ox.ac.uk), ref: R80951/RE001

Study design

Retrospective cohort study

Primary study design

Observational

Secondary study design

Retrospective cohort study

Study setting(s)

Medical and other records

Study type(s)

Other

Participant information sheet

Not applicable (retrospective study)

Health condition(s) or problem(s) studied

People with chronic liver disease, including alcohol-related liver disease (ALD), chronic hepatitis B infection (CH-B), chronic hepatitis C infection (CH-C), and non-alcoholic fatty liver disease (NAFLD)

Interventions

Using data from the Primary Care Sentinel Cohort (PCSC) of the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance centre (RSC) for the period between the 1st January 2012 and 31st December 2022. Data will be extracted retrospectively at the time of the start of the study.

Intervention Type

Other

Primary outcome measure

Number of doses of hepatitis A vaccination measured using patient records at a single time point

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

31/03/2022

Completion date

31/08/2024

Eligibility

Key inclusion criteria

We will include adults registered in general practices within the RSC network, with a diagnosis of CLD, as defined by our ontology, within the period between the 1st January 2012 and 31st December 2022. The following inclusion criteria will be applied:

People registered in the RSC general practices, aged 18 years of age and older, with a diagnosis of CLD. Our ontology for CLD includes: Alcoholic liver disease (ALD), chronic hepatitis B (CH-B), chronic hepatitis C (CH-C), non-alcoholic fatty liver disease, Wilson's Disease, haemochromatosis, autoimmune hepatitis (AIH), primary sclerosing cholangitis (PSC) and primary biliary cholangitis (PBC).

Participant type(s)

Population

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1,650

Total final enrolment

13875

Key exclusion criteria

1. Patients with recorded contraindications to the Hep A vaccine (confirmed anaphylactic reaction to a previous dose of Hep A containing vaccine, or to any of its components).
2. Records of administration of post-infection or risk-of-infection immunoglobulins.

Date of first enrolment

06/06/2023

Date of final enrolment

06/06/2023

Locations

Countries of recruitment

England

United Kingdom

Wales

Study participating centre

Clinical Informatics and Health Outcomes Research Group, Nuffield Department of Primary Care Health Sciences at the University of Oxford

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Sponsor information**Organisation**

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Sponsor type

University/education

ROR

<https://ror.org/052gg0110>

Funder(s)**Funder type**

Industry

Funder Name

GlaxoSmithKline Biologicals

Alternative Name(s)

GSK Belgium, GlaxoSmithKline Biologicals SA, GlaxoSmithKline Biologicals SAS, GlaxoSmithKline (GSK) Biologicals, GSK Biologicals, GSK

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Belgium

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/03/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository, at the ORCHID database hosted by the Nuffield Department of Primary Care Health Sciences at the University of Oxford (<https://orchid.phc.ox.ac.uk/>)

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)		05/09/2023	15/09/2023	No	No
Basic results	version 5.2	04/12/2024	17/01/2025	No	No