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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

Registration date
12/10/2023

Overall study status
Completed

Last Edited
27/01/2025

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Observational

Study design
Retrospective cohort study

Study type(s)
Other

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

Key secondary outcome(s)
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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
University of Oxford

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

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?
Basic results	version 5.2	04/12/2024	17/01/2025	No	No

Protocol (preprint)	05/09/2023	15/09/2023	No	No