AlcoholicLiverDisease: Alcoholic liver disease treatment effects

Information about Protocol content.

An observational study plan should be documented in the form of a protocol created prior to executing a study. At a minimum, a protocol describes the primary study question, the approach, and metrics that will be used to answer the question. The study population should be described to a level of detail such that the study population may be fully reproduced by others. In addition, all methods or statistical procedures and the form of expected study results such as metrics, tables and graphs should be described. Often, a protocol will also describe a set of pre-analyses designed to assess the feasibility or statistical power of the study. Furthermore, protocols may contain descriptions of variations on the primary study question referred to as sensitivity analyses. Sensitivity analyses are designed to evaluate the potential impact of study design choices on the overall study findings and should be described in advance whenever possible. Sometimes unanticipated issues arise that may necessitate a protocol amendment after a protocol is completed. If this becomes necessary, it is critical to document the change and the reasons for the change in the protocol itself. Particularly in the case of PLE or PLP, a completed study protocol will ideally be recorded in an independent platform (such as clinicaltrials.gov or OHDSI’s studyProtocols sandbox) where its versions and any amendments can be tracked independently with timestamps. It is also often the case that your institution or the owner of the data source will require the opportunity to review and approve your protocol prior to study execution.

Source: <https://ohdsi.github.io/TheBookOfOhdsi/StudySteps.html> Chapter 19.1.3

Study Design and Feasibility

The study feasibility stage (or the pre-study stage) defines a study question and describes the process to answer this question via the study protocol. This stage focuses on assessing the feasibility of executing the study protocol across participating sites.

The outcome of the feasibility stage is the generation of a finalized protocol and study package that is published ready for network execution. The formal protocol will detail the study team, including the designated study lead (often the corresponding author for publication purposes), and information on the timeline for the study. The protocol is a critical component for additional network sites to review, approve and execute the full study package on their CDM data. A protocol must include information on study population, the methods being used, how the results will be stored and analyzed as well as how the study results will be disseminated after completion (e.g. a publication, presentation at scientific conference, etc.).

The feasibility stage is not a well-defined process. It is a series of activities that are highly dependent on the type of study proposed. At a minimum, the study lead will spend time identifying relevant network sites that contain the targeted patient population(s) with required drug exposure, procedure information, condition or demographics information. Where possible, the study lead should provisionally use their own CDM to design the target cohorts. However, there is no requirement that a study lead have access to a live OMOP CDM with real patient data to run a network study. The study lead may design their target cohort definition using synthetic data (e.g. CMS Synthetic Public Use Files, SyntheticMass from Mitre or Synthea) and ask collaborators at OHDSI network sites to help with validating the feasibility of this cohort. Feasibility activities may include asking collaborators to create and characterize cohorts using JSON files of cohort definitions from ATLAS or testing study R packages and running initial diagnostics as discussed in Chapter 19. At the same time, the study lead may need to initiate any organization-specific processes to approve an OHDSI study at the organizing institution, if required – such internal Institutional Review Board approval. It is the responsibility of the study lead to complete these organization-specific activities during the feasibility phase.

Source: <https://ohdsi.github.io/TheBookOfOhdsi/NetworkResearch.html> Chapter 20.3.1

Prepared on: 2020-09-22

Created by: Timo Itzel, Andreas Teufel

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# List of Abbreviations

| Abreviation | Phrase |
| --- | --- |
| AH | Alcoholic Hepatitis |
| ALD | Alcoholic Liver Diseases |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

# Responsible Parties

Author: Prof. Dr. Dr. Andreas Teufel, Medical Faculty Mannheim, Heidelberg University, Germany

Investigators: Timo Itzel, Andreas Teufel

Reviewers:

# Abstract

Screening under different conditions the survival of the patients with alcoholic liver disease to figure out therapeutic options for the risk of bleeding.

# Rationale & Background

Alcoholic liver disease (ALD) has the highest mortality of the alcoholism associated diseases and remains a major cause of liver-related mortality worldwide. The first line of treatment for ALD and the most important one is alcohol abstinence, which can be aided by psychotherapy or pharmacologic agents. Other standard treatments for ALD include nutritional therapy, pharmacological therapy and liver transplant, however, these standard treatments have not changed in the last 40 years due to the lack of an experimental models for ALD and because of the difficulty to perform clinical trials in ALD patients.

ALD encompasses a broad spectrum of conditions ranging from reversible fatty liver to alcoholic hepatitis (AH), and cirrhosis. The treatment of AH with current existing therapies has conflicting results. Corticosteroids are the main treatment options for patients with AH and is considered to have survival benefit, however, the results from various studies are mixed and 40% of AH patients do not respond to corticosteroid treatment [3]. Pentoxifylline is an alternative to corticosteroids treatment, however, in a meta-analysis and systematic reviews it failed to improve the overall survival rate but in a study that compared pentoxifylline to prednisolone, pentoxifylline showed better efficacy. The other therapies used in the treatment of ALD also have conflicting results and there is a need for confirmative studies.

The aim of this project is to conduct an analysis of survival dependent on co-existing conditions or medications considering of patients diagnosed with ALD by extracting a large number of electronic health records from OHDSI databases. As a benefit to patients the obtained results be lead to recommendations on treatment or co-medication for these patients who otherwise have often limited treatment options.

# Study Objective

Screening under different conditions the survival of the patients with alcoholic liver disease to figure out therapeutic options for the risk of bleeding.

# Research Methods

## Study Design

## Study Population

The initializing cohort is based on the first condition of ‘Alcoholic liver damage’ (201612) or any of the downstream codes after 1st of January 2000.

For the cohort (No Hepatitis), we exclude all patients of the initial cohort that contains the condition ‘Viral hepatitis’ (4291005) or any of the downstream codes.

The reduction of the cohorts Hepatitis B; Hepatitis C were done exclusively annotation of one of the 2 following condition lists.

### Hepatitis B:

**CodeSet Title**

192240 Chronic viral hepatitis B with hepatitis D

194574 Chronic type B viral hepatitis

197795 Acute type B viral hepatitis

198683 Viral hepatitis B without hepatic coma

439674 Chronic viral hepatitis B without delta-agent

439675 Acute hepatitis B with delta agent (coinfection) with hepatic coma

4009793 Chronic aggressive type B viral hepatitis

4027854 Acute fulminating type B viral hepatitis

4341652 Acute hepatitis B with hepatitis D

4296554 Chronic persistent type B viral hepatitis

4281232 Type B viral hepatitis

4203326 Anicteric type B viral hepatitis

4173584 Chronic active type B viral hepatitis

37017654 Occult chronic type B viral hepatitis

40482214 Hepatitis B associated with Human immunodeficiency virus infection

40483136 Hepatitis B and hepatitis C

40488872 Reactivation of hepatitis B viral hepatitis

### Hepatitis C:

**CodeSet Title**

192242 Acute hepatitis C

197494 Viral hepatitis C

198964 Chronic hepatitis C

439672 Viral hepatitis C with coma

763021 Chronic viral hepatitis C with hepatic coma

35624866 Chronic hepatitis C caused by hepatitis C virus genotype 6

35624867 Chronic hepatitis C caused by hepatitis C virus genotype 5

35625040 Chronic hepatitis C caused by Hepatitis C virus genotype 3

35625139 Chronic hepatitis C caused by Hepatitis C virus genotype 2

35625140 Chronic hepatitis C caused by Hepatitis C virus genotype 4

35625141 Chronic hepatitis C caused by Hepatitis C virus genotype 1

35625295 Chronic hepatitis C caused by Hepatitis C virus genotype 1b

35625296 Chronic hepatitis C caused by Hepatitis C virus genotype 1a

40483136 Hepatitis B and hepatitis C

43531723 Cirrhosis of liver due to chronic hepatitis C

44809233 Hepatitis C genotype 1

44809234 Hepatitis C genotype 2

44809236 Hepatitis C genotype 3

44809237 Hepatitis C genotype 4

44809238 Hepatitis C genotype 5

44809239 Hepatitis C genotype 6

45757726 Chronic hepatitis C with stage 3 fibrosis

45766656 Chronic hepatitis C with stage 2 fibrosis

45769525 Chronic active hepatitis C

45773146 Reactivation of hepatitis C viral hepatitis

After generating these cohorts all patients were dropped that died before the first initial condition after 1st of January 2000 were raised.

# Data Analysis Plan

# Strengths & Limitations

## Strengths

* …

## Limitations

* …

# Protection of Human Subjects

In this study, we only use summarized information to describe the cohort and the overall description of the distributions of the cohort for every analysis. An identification of any patient is not possible.

# Plans for Disseminating & Communicating Study Results

# References

[3] …

# Appendices

## Study Generation Version Information

## Code list