

# Study of the risk of punctured lungs (pneumothorax) in cannabis smokers

<b>Submission date</b> 02/03/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/03/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/03/2023	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cannabis, known more commonly as weed, pot or dope, is a psychoactive compound and the most widely used illegal drug in the UK. Despite the growing interest in its therapeutic potential, cannabis smoke shares much of the chemical profile and carcinogens as tobacco, and yet the smoking technique – deeper inhalation and longer breath-holding time – results in greater deposition of particulates in the airway. Consequently, the smoke from a single cannabis ‘joint’ may be equivalent to smoking more than 20 tobacco cigarettes daily. Therefore, although cannabis is often smoked less frequently than tobacco, it has the potential to be at least equally harmful. Unsurprisingly, considerable evidence links cannabis use to respiratory diseases. Given that one in 13 adults report smoking cannabis in the last year, it is crucial that we fully explore the risks of cannabis use on the respiratory system.

Pneumothorax occurs when there is air in the pleural space owing to lung or chest wall perforation. Spontaneous perforation of the lung can occur due to genetic or environmental factors including smoking. While the role of tobacco smoke in emphysema and secondary pneumothorax is well-appreciated, relatively few studies have explored the relationship between cannabis and pneumothorax. The aim of this study is to estimate the odds ratio of pneumothorax in cannabis smokers.

### Who can participate?

Patients aged 16-50 years seen in the Cambridge Pneumothorax Clinic and matched individuals recruited from unrelated clinics at Cambridge University Hospitals (CUH) NHS Foundation Trust

### What does the study involve?

The researchers will collect data for up to 450 patients (aged 16 to 50 years) seen in the Cambridge Pneumothorax Clinic. An equal number of individuals, matched for age, sex, socio-economic status and geography, will be recruited from unrelated hospital services. These patients will be asked to complete a single, anonymised questionnaire on their smoking habits and whether they had ever suffered a pneumothorax.

What are the possible benefits and risks of participating?

This study will be the first of its kind in the UK and the largest in the world. It will provide evidence of use to the UK population, policymakers, and inform NHS service provision. Being an anonymous non-interventional study, there are no risks to the participants.

Where is the study run from?

Cambridge Institute for Medical Research (CIMR) (UK)

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

February 2022 to October 2024

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Prof.r Stefan Marciniak, stefan.marciniak@nhs.net

## Contact information

### Type(s)

Principal Investigator

### Contact name

Prof Stefan Marciniak

### ORCID ID

<http://orcid.org/0000-0001-8472-7183>

### Contact details

Cambridge Institute for Medical Research (CIMR)

Keith Peters Building

University of Cambridge

Cambridge

United Kingdom

CB2 0XY

+44 (0)1223 762660

stefan.marciniak@nhs.net

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

311724

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

## Study information

### Scientific Title

What is the risk of pneumothorax in cannabis smokers?

### Acronym

RoPiCS

### Study objectives

Cannabis smoking increases the risk of pneumothorax.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Provisional opinion from London - Brighton & Sussex Research Ethics Committee

### Study design

Retrospective hospital-based case-control study

### Primary study design

Observational

### Secondary study design

Case-control study

### Study setting(s)

Hospital

### Study type(s)

Other

### Participant information sheet

Not available in web format, please use contact details to request participant information sheet

### Health condition(s) or problem(s) studied

Pneumothorax

### Interventions

This study will collect data retrospectively for up to 450 patients (aged 16 to 50 years) seen in the Cambridge Pneumothorax Clinic. An equal number of controls, matched for age, sex, socio-economic status and geography, will be recruited from unrelated hospital services. These patients will be asked to complete a single, anonymised questionnaire on their smoking habits and whether they had ever suffered a pneumothorax.

### Intervention Type

Other

**Primary outcome measure**

Relative risk of pneumothorax in cannabis smokers measured using unconditional logistic regression adjusted for possible confounders including the matching variables (age, sex and area of residence) and smoking habits at a single timepoint (cases: first attendance at pneumothorax; controls: at completion of the questionnaire in a non-pneumothorax clinic). The odds ratio and associated 95% confidence limits will be estimated. All analyses will be carried out in R using the glm command implemented in the stats package.

**Secondary outcome measures**

1. Cannabis and tobacco usage in the local population measured using a bespoke questionnaire at attendance at a non-pneumothorax clinic on a single occasion
2. The potential interaction between cannabis and tobacco smoking in pneumothorax evaluated by including an interaction term in the logistic regression model at first attendance at pneumothorax (cases) or at completion of the questionnaire in a non-pneumothorax clinic (controls)

**Overall study start date**

01/02/2022

**Completion date**

01/10/2024

**Eligibility****Key inclusion criteria**

1. Patients aged 16-50 years seen in the Cambridge Pneumothorax Clinic
2. Matched individuals recruited from unrelated clinics at Cambridge University Hospitals (CUH) NHS Foundation Trust

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

16 Years

**Upper age limit**

50 Years

**Sex**

Both

**Target number of participants**

900

**Key exclusion criteria**

Traumatic pneumothorax

**Date of first enrolment**

01/04/2023

**Date of final enrolment**

01/10/2024

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Cambridge University Hospitals NHS Foundation Trust**

Cambridge Biomedical Campus

Hills Road

Cambridge

United Kingdom

CB2 0QQ

## **Sponsor information**

**Organisation**

Cambridge University Hospitals NHS Foundation Trust

**Sponsor details**

Addenbrooke's Biomedical Campus

Hills Road

Cambridge

England

United Kingdom

CB2 0QQ

+44 (0)1223 245151

stephen.kelleher3@nhs.net

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.cuh.org.uk/>

**ROR**

<https://ror.org/04v54gj93>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

01/10/2025

## Individual participant data (IPD) sharing plan

Because the questionnaire will include topics that have the potential to be sensitive or embarrassing and may disclose illegal activity (class B drug abuse), the data will not be made externally available except in the context of the planned publication.

Data will be fully anonymised for use in the study, and will include: cannabis and tobacco use (current, previous, never), including the quantity smoked, sex, ethnicity, and age in 5-year bins (16-20, 21-25, etc). Controls, recruited from unrelated outpatient services will be matched to the case population demographically by an anonymised questionnaire. For individuals who might not adequately understand verbal explanations or written information given in English, or who have special communication needs, the researchers have taken steps to produce versions of the questionnaire in Polish and Romanian to reflect the demographics of patients seen in the Cambridge Pneumothorax Clinics. For the visually impaired, they will take measures to ensure a private environment is available to facilitate reading the questionnaire aloud to the participant. Informed consent will be obtained from all prospective participants both verbally and through a field on the questionnaire. Only participants who have given consent for the use of their data and who are of 16-50 years will be included. No identifiable data will be retained. Data will be stored electronically in a fully anonymised form.

## IPD sharing plan summary

Not expected to be made available