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

Submission date 02/03/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/03/2023	**Overall study status** Ongoing	
Last Edited 07/11/2025	**Condition category** Respiratory	

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 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Stefan Marciniak, stefan.marciniak@nhs.net

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
311724

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

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

Study type(s)
Other

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(s)
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.

Key secondary outcome(s))

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)

Completion date
31/10/2026

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Upper age limit
50 years

Sex
All

Key exclusion criteria
Traumatic pneumothorax

Date of first enrolment
01/04/2023

Date of final enrolment
01/10/2024

Locations

Countries of recruitment
United Kingdom

England

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

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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