ISRCTN16961081 https://doi.org/10.1186/ISRCTN16961081

Effect of smoking and smoking cessation on the outcome of orthopaedic and hand surgical operations

Submission date	**Recruitment status**	[_] Prospectively registered
06/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/09/2021	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2025	Surgery	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Smoking has many adverse effects on surgical patients. After surgical operations, smokers have more complications than nonsmokers. Some complications, especially deep infections are difficult and costly to treat. Fortunately, these detrimental effects and complications caused by smoking can be decreased by smoking cessation. Orthopaedic and hand surgical patients are invited in the research aiming to study the effect of smoking and smoking cessation on the incidence of complications. Further aims of the study are to determine the effect and feasibility of smoking cessation intervention on reducing smoking, and factors predicting success in smoking cessation, and to determine which other factors, in addition to smoking, explain the incidence of complications.

Who can participate?
Orthopaedic and hand surgical patients visiting the orthopaedic or hand surgical outpatient department and who are put on the waiting list for elective orthopaedic or hand surgical operation in Päijät-Häme Central Hospital, Lahti, Finland can participate in the study.

What does the study involve?
Study patients fill in a self-reported questionnaire. Additional and clarifying information such as diagnoses of chronic diseases and prescribed medication are collected from medical records of study patients. Smokers receive information about the benefits of smoking cessation and are encouraged to quit. Medication or nicotine replacement therapy is prescribed. Laboratory tests are taken two weeks before and two weeks after surgery. Follow-up phone calls are made at 3, 6, and 12 months after surgery. The primary outcome is any complication of the operation, defined as a prolonged stay in hospital or any additional visit to or measure taken by a health service during the 12 months after surgery. Data on complications are mainly obtained from personal health records and from the information received at the follow-up phone calls, and the rest of data will be collected from the register of healthcare-associated infections. Secondary outcomes are the number and types of complications. Associations of smoking status and other effective factors with complications will be analysed using appropriate statistical methods.

What are the possible benefits and risks of participating?
The patients can get the results of the laboratory tests taken for this study, if they ask. Smoking patients are supported to stop smoking and if succeeded, their outcome of the operation could be better. All patients taking part in the complete study, are told the results and conclusions after completion of the study. Participants fill in a self-reported questionnaire collecting detailed background information on chronic diseases, medication, socio-economic status, physical activity, present and past smoking, and use of alcohol. Laboratory tests are taken 2 weeks before and after the operation. Patients are called at 3, 6, and 12 months after surgery and asked about possible problems or complications. There are no other disadvantages caused by this study for the patients.

Where is the study run from?
Päijät-Häme Central Hospital, Lahti, Finland

When is the study starting and how long is it expected to run for?
November 2014 to December 2026

Who is funding the study?
The government of Finland (State Research Funding), the Foundation of the Finnish Anti-Tuberculosis Association, Doctors Against Tobacco Network in Finland, Finnish Lung Health Association (FILHA Ry), Erkki Poikonen Foundation, and Päijät-Häme Doctors' Association.

Who is the main contact?
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Additional identifiers

Protocol serial number
D938/02.05.01.00.03/2018

Study information

Scientific Title
The effect on complications and feasibility of smoking cessation interventions performed on orthopaedic and hand surgical patients before operation

Study objectives
1. Smoking patients have more complications compared with non-smoking patients
2. Patients continuing smoking despite smoking cessation intervention have more complications than initially smoking patients who are stopping smoking because of the intervention
3. Further aims of the study are to clear the feasibility of this kind of preoperative smoking cessation intervention and its effect on reducing smoking and to clear which factors predict success in smoking cessation.
4. An additional aim of the study is to compare the incidence of different types of complications in the whole study population and in different subgroups of orthopaedic and hand surgical patients who are smokers, non-smokers and patients who stop smoking during the preoperative intervention.
5. A further aim of the study is to determine which other factors in addition to smoking, such as chronic diseases and medications, explain the incidence of complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/09/2015, Regional Ethical Committee of Tampere University Hospital (Tays Expert Responsibility Area Ethics Committee, PL 2000, 33521 Tampere, Finland; +358331166910; kirsi.kohonen@pshp.fi), ref: R 15129

Study design
Single-centre interventional study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Complications after orthopaedic and hand surgery of non-smoking patients and of patients stopping smoking because of intervention and of patients continuing smoking in spite of intervention

Interventions
Smokers are given verbal and written information about health and economic benefits of smoking cessation, and encouraged to quit smoking. The Fagerström Test for Nicotine Dependence is conducted to estimate the level of nicotine dependence of smokers. If a smoker has moderate nicotine addiction, nicotine replacement therapy is recommended. Prescription medication to aid smoking cessation is considered if a participant has strong nicotine dependence.

The smoking cessation intervention is given in the outpatient department, by the surgeon or the nurse, or by both. In discussions with smokers, the aim is to share information, motivate, give social support to quit smoking and in all help the patient to stop smoking. The intervention is performed during an outpatient appointment when the patient is registered on the waiting list and also during the preoperative visit. After surgery, when the stitches are removed, Hb-CO and U-Cot tests are repeated to ensure participants' smoking status and to verify successful smoking cessation.

Participants are followed up to 12 months after surgery. Participants receive a phone call or letter at 3, 6, and 12 months after surgery, asking if any problems or complications have occurred.

Intervention Type
Behavioural

Primary outcome(s)
Any complication occurring within 12 months after surgery. Complications are recorded when the study patient is leaving the hospital, when the stitches are removed and at follow-up phone calls at 3, 6 and 12 months after surgery.

Key secondary outcome(s))
1. The number and types of complications (for example rapidly occurring complications, repeat surgery, and infections, stratified by types of surgery) are considered as secondary outcomes. They are recorded when the study patient is leaving the hospital, when the stitches are removed and at follow-up phone calls at 3, 6 and 12 months after surgery.
2. Successful smoking cessation is a feasibility outcome, and it is defined and recorded on ground of the announcement of the patient at the preoperative visit and on grounds of the laboratory tests taken at the preoperative visit and when the stitches are removed and on ground of the announcement of the patient at follow-up phone calls at 3, 6 and 12 months after surgery.

Completion date
31/12/2026

Eligibility

Key inclusion criteria

Patients of at least 18 years of age visiting the orthopaedic or hand surgical outpatient department and who are on the waiting list for elective orthopaedic or hand surgery so that the planned surgery is directed at the bone in Päijät-Häme Central Hospital, Lahti, Finland.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
550

Key exclusion criteria
Patients under 18 years of age, patients with an acute fracture, and patients awaiting other types of surgery

Date of first enrolment
27/10/2015

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
Finland

Study participating centre
Päijät-Häme Central Hospital
Päijät-Häme Central Hospital
Keskussairaalankatu 7
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Sponsor information

Organisation
Tampere University Hospital

ROR
https://ror.org/02hvt5f17

Organisation
Päijät-Hämeen Keskussairaala

ROR
https://ror.org/02v92t976

Funder(s)

Funder type
Government

Funder Name
The Government of Finland (State Research Funding)

Funder Name
The Foundation of the Finnish Anti-Tuberculosis Association

Funder Name
Doctors Against Tobacco Network in Finland

Funder Name
Filha

Alternative Name(s)
Finnish Anti-Tuberculosis Association, Finnish Lung Health Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Finland

Funder Name
Erkki Poikonen Foundation

Funder Name
Päijät-Häme Doctors' Association

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/08/2022	12/12/2022	Yes	No