

Prevention of nicotine-associated morbidity by smoking cessation counselling in trauma patients in an emergency department

Submission date 11/08/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/01/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/07/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Emergency departments (EDs) are suitable settings for screening and health promotion. A number of studies showed effective strategies for the prevention of the negative consequences of alcohol consumption. There is little evidence about the benefits of screening and prevention programs for tobacco use. Therefore, the aim of this study is to find out whether smokers in an emergency department benefit from a tobacco control program.

Who can participate?

Patients aged over 18 in an emergency department

What does the study involve?

Participants are randomly allocated to one of two groups. One group receives a motivational interview on site and up to four booster telephone calls intended to motivate smoking patients to quit. They also receive an information leaflet and, if desired, nicotine patches and gum. The other group receives the information leaflet only. Smoking rates are compared between the two groups. As there is evidence from other settings that tobacco control interventions show positive effects not only in the short term (some weeks or months) but also in the long-term (several years), all participants receive a postal questionnaire 10 years later to assess the long-term effects of the intervention.

What are the possible benefits and risks of participating?

All participants undergo screening for tobacco use and receive the information leaflet. Those participants allocated to the tobacco control program also receive a motivational interview. Participants in the control group are offered this program at the end of the study. There are no risks reported in regard to tobacco control programs.

Where is the study run from?

Charité – Universitätsmedizin Berlin (Germany)

When is the study starting and how long is it expected to run for?
October 2005 to June 2016

Who is funding the study?
German Cancer Aid

Who is the main contact?
Dr Bruno Neuner
anaesth@charite.de

Contact information

Type(s)
Scientific

Contact name
Dr Bruno Neuner

Contact details
Department of Anaesthesiology and Intensive Care Medicine
Charite Universitaetsmedizin Berlin
Augustenburgerplatz 1
Berlin
Germany
13353
+49 (0)30 450 551001
anaesth@charite.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prevention of nicotine-associated morbidity by smoking cessation counselling in trauma patients in an emergency department

Acronym
TED study (Tobacco control in an urban Emergency Department)

Study objectives

The aim of this study is to investigate whether a 20 to 30 minutes counselling in smokers followed by four 5 to 15 minutes booster session by telephone leads to a significant reduction in the number of cigarettes in smokers ambivalent concerning their smoking and a significant rate of abstaining in those smokers who actively try to quit smoking.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Original study: Ethics Committee of the Charité Universitätsmedizin, Berlin, 19/11/2004, ref: EA1/23/2004
2. 10 years follow-up postal survey: Ethics Committee of the Charité Universitätsmedizin, Berlin, 08/09/2015, ref: EA1/238/15

Study design

Randomised controlled trial (TED study) and postal survey (10-years follow-up)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Smoking addiction

Interventions

Participants are randomised to receive either:

1. A 20 to 30 minutes counselling session followed by four 5 to 15 minutes booster session by telephone
2. Care as usual

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Significant rates of abstainers in those smokers who actively try to quit smoking

Secondary outcome measures

Reduction in the number of cigarettes in smokers ambivalent concerning their smoking

Overall study start date

01/10/2005

Completion date

30/06/2016

Eligibility**Key inclusion criteria**

1. Patients in an emergency department
2. Aged over 18

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1044

Key exclusion criteria

1. Under 18 years of age
2. Altered mental status that precluded consent
3. Medically unstable
4. In significant pain
5. Were intoxicated by alcohol or drugs
6. Were non-German speaking

Date of first enrolment

01/10/2005

Date of final enrolment

21/12/2006

Locations**Countries of recruitment**

Germany

Study participating centre**Charité – Universitätsmedizin Berlin**

Department of Anaesthesiology and Operative Intensive Care Medicine

Campus Charité Mitte

Charitéplatz 1

Berlin

Germany

10117

Sponsor information

Organisation

Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

Sponsor details

c/o Dr Bruno Neuner and Prof. Claudia Spies

Department of Anaesthesiology and Operative Intensive Care Medicine

Campus Charité Mitte, Charité – Universitätsmedizin Berlin

Charitéplatz 1

Berlin

Germany

10117

Sponsor type

University/education

Website

<https://anaesthesieintensivmedizin.charite.de/>

ROR

<https://ror.org/001w7jn25>

Funder(s)

Funder type

Charity

Funder Name

Deutsche Krebshilfe Grant-No.: DKH-106730 (TED-study) and DKH-111507 (10-years follow-up)

Alternative Name(s)

Stiftung Deutsche Krebshilfe, German Cancer Aid

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Germany

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

31/10/2017

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2009		Yes	No