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Outcome of nicotine replacement therapy in the patients admitted to Intensive Care Unit

Submission date	Recruitment status	[ ] Prospectively registered
30/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/08/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/05/2014	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Outcome of nicotine replacement therapy in the patients admitted to Intensive Care Unit: a randomised case-control double blinded prospective trial

Study objectives

Nicotine replacement therapy decreases the length of Intensive Care Unit (ICU) stay and increases ventilator free days in intubated patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent Institutional Review Board (chaired by Dr. Joseph Chang, M.D) approved on the 1st December 2009 (ref: 2009.23)

Study design
Randomised case-control double blinded prospective trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
Interventional arm:
After randomising patients into case and control, we applied nicotine patch containing nicotine 21 mg on the skin for patients who were cases. We applied it every day until patient was discharged from the ICU, transferred to General medical floor or until 10 weeks (if the patient was in ICU for 10 weeks).

Control arm:
For the control group the frequency and the duration was same but the patch did not contain nicotine.

Patients were unaware if they had nicotine patch or placebo patch. Patches were applied within 24 - 48 hours of ICU admission. Twenty four hours after the application of patch data was collected. The data collection researcher did not know which patient had nicotine patch and which patient had placebo. Patient was only followed up until the ICU stay.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Nicotine replacement therapy

Primary outcome(s)

1. Decreased ICU stay, measured after the patient is out of ICU
2. Increased ventilator free days, measured when patient is breathing without the help of ventilator

Key secondary outcome(s))
Decreased use of sedation and analgesia, measured at the end of ICU stay

Completion date
30/07/2009

Eligibility

Key inclusion criteria
1. Smoker (greater than 1 pack per day [ppd] for greater than 1 year)
2. Admitted to ICU
3. Consent required either from patient or from surrogate
4. Aged greater than 18 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnant
2. Myocardial infarction (MI) in last 2 weeks
3. Uncontrolled or serious arrhythmia
4. Severe allergic reaction to nicotine or patch
5. Peptic ulcer disease
6. Hyperthyroidism

Date of first enrolment
01/01/2009

Date of final enrolment
30/07/2009

Locations

Countries of recruitment
United States of America

Study participating centre
St. Barnabas Hospital
Bronx, New York
United States of America
10457

Sponsor information

Organisation
St Barnabas Hospital (USA)

ROR
https://ror.org/02952et24

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (USA)

Results and Publications

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	01/10/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes