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

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| **Submission date**<br>30/06/2010 | **Recruitment status**<br>No longer recruiting |
| **Registration date**<br>10/08/2010 | **Overall study status**<br>Completed |
| **Last Edited**<br>15/05/2014 | **Condition category**<br>Mental and Behavioural Disorders |

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## 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 below to request a patient information sheet

## 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 measure
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

### Secondary outcome measures
Decreased use of sedation and analgesia, measured at the end of ICU stay

### Overall study start date
01/01/2009

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
40

### 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)

### Sponsor details
4422, Third Avenue
Bronx, NY
United States of America
10457

### Sponsor type
Hospital/treatment centre

### Website
http://www.stbarnabashospital.org/

### ROR
https://ror.org/02952et24

## Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded (USA)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**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 |