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 [] Statistical analysis plan Registration date Overall study status 10/08/2010 Completed [X] Results [] Individual participant data **Last Edited** Condition category Mental and Behavioural Disorders 15/05/2014

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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