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The evaluation of the efficacy and safety of a transdermal delivery system of nicotine /mecamylamine in cigarette smokers

Submission date 03/05/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/06/2006	**Overall study status** Completed	
Last Edited 19/03/2010	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives
To determine the efficacy and safety of nicotine transdermal therapy co-administered with the nicotine antagonist, mecamylamine; as compared to a nicotine transdermal patch alone (21 mg nicotine + 6 mg mecamylamine, 21 mg nicotine + 3 mg mecamylamine, and 21 mg nicotine + 0 mg mecamylamine).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the West Virginia University's Institutional Review Board in 1997, reference number: HS13781

Study design
Multicenter (n=4), double-blind, randomized, parallel group, repeat dose study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cigarette smoking

Interventions
Treatment was administered for the first six weeks of the 8-week study. Patients were instructed to continue smoking for the first two weeks of treatment.
Patients were randomised into one of the following groups:
1. 21 mg nicotine + 6 mg mecamylamine
2. 21 mg nicotine + 3 mg mecamylamine
3. 21 mg nicotine + 0 mg mecamylamine

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Mecamylamine, nicotine

Primary outcome measure
Analysis of the four-week continuous abstinence for the intent-to-treat population using the slip definition, which allows smoking in the first two weeks after the quit date.

Secondary outcome measures
Analysis of the four-week continuous abstinence for the intent-to-treat population using the strict definition (no smoking after the quit date).

Overall study start date
01/01/1997

Completion date
31/12/1998

Eligibility

Key inclusion criteria
1. Males or females motivated to quit smoking between the ages of 18 and 70 years
2. Smoked at least 20 cigarettes a day for three years or more (smoking confirmed via expired CO level >10 ppm).
All subjects had normal blood pressure and heart rate, weighed more than 100 pounds and typically no more than 130% of their ideal body weight, and expressed willingness to quit smoking on the specified target quit date (TQD). They were not currently using smokeless tobacco or other nicotine products. A detailed medical history, routine physical examination, laboratory tests and electrocardiogram (ECG) confirmed that subjects were in general good health. All women had a negative pregnancy test and agreed to use a medically accurate contraceptive method.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
375

Key exclusion criteria

Participants were excluded if they had a history of significant hepatic, renal, endocrine, cardiac, psychiatric, gastrointestinal, pulmonary, or metabolic disorder including hyperthyroidism, pheochromocytoma, diabetes, severe coronary insufficiency, recent myocardial infarction (within 90 days), glaucoma, cerebrovascular disease, stroke, chronic renal failure, prostatic hypertrophy, prostatic disease, bladder neck obstruction, urine retention, urethral stricture, a history of atopic or eczematous dermatitis, psoriasis, or altered skin condition at patch application site.

Date of first enrolment
01/01/1997

Date of final enrolment
31/12/1998

Locations

Countries of recruitment
United States of America

Study participating centre
University of Maryland
Maryland
United States of America
20742

Sponsor information

Organisation
Elan Corp (USA)

Sponsor details
Medical Affairs
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Sponsor type
Industry

ROR
https://ror.org/013t2n957

Funder(s)

Funder type
Industry

Funder Name
Elan Corp (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	01/05/2007		Yes	No